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42 CFR Parts 405, 410, 412, et al.
Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education; Fiscal Year 2002 Rates, Etc.; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 413, 482, 485, and 486

[CMS 1131–F, CMS 1158–F, and CMS 1178–F]

RINs 0938–AK20; 0938–AK73; and 0938–AK74

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education: Fiscal Year 2002 Rates; Provisions of the Balanced Budget Refinement Act of 1999; and Provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rules.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems for operating and capital costs to: implement applicable statutory requirements, including a number of provisions of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000 (Public Law 106–554); and implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this final rule, we describe changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes apply to discharges occurring on or after October 1, 2001. We also set forth the rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the prospective payment systems.

We are making changes to the policies governing payments to hospitals for the direct costs of graduate medical education and critical access hospitals.

Lastly, we are responding to public comments received on the following two related interim final rules that we published in the **Federal Register** and finalizing those interim rules:

• An August 1, 2000 interim final rule with comment period (65 FR 47026, HCFA–1131–IFC) that implemented, or conformed the regulations to, certain statutory provisions relating to Medicare payments to hospitals for inpatient services that were contained in the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Public Law 106–113), and that were effective during FY 2000. These provisions related to reclassification of hospitals from urban to rural status, reclassification of certain hospitals for purposes of payment during fiscal year 2000, critical access hospitals, payments to hospitals excluded from the prospective payment system, and payments for indirect and direct graduate medical education costs.

• A June 13, 2001 interim final rule with comment period (66 FR 32172, HCFA–1178–IFC) that implemented, or conformed the regulations to, certain statutory provisions relating to Medicare payments to hospitals for inpatient services that were contained in Public Law 106–554, and that were effective prior to passage of Public Law 106–554 on December 21, 2000; on April 1, 2001; or on July 1, 2001. Many of the provisions of Public Law 106–554 modified changes to the Social Security Act made by Public Law 106–113 or the Balanced Budget Act of 1997 (Public Law 105–33), or both.

EFFECTIVE DATE: The provisions of this final rule are effective October 1, 2001. This rule is a major rule as defined in 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), we are submitting a report to Congress on this rule on August 1, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Phillips, (410) 786–4548, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, Hospital Geographic Reclassifications, Sole Community Hospitals, Disproportionate Share Hospitals, and Medicare-Dependent, Small Rural Hospitals Issues; Tzvi Hefter, (410) 786–4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education and Critical Access Hospitals Issues.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Summary

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of hospital inpatient stays under a prospective payment system. Under these prospective payment systems, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs). Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that DRG.

Under section 1886(d)(1)(B) of the Act in effect without consideration of the amendments made by Public Law 105–33, Public Law 106–113, and Public Law 106–554, certain specialty hospitals are excluded from the hospital inpatient prospective payment system: psychiatric hospitals and units, rehabilitation hospitals and units, children's hospitals, long-term care hospitals, and cancer hospitals. For these hospitals and units, Medicare payment for operating costs is based on reasonable costs subject to a hospital-specific annual limit, until the payment provisions of Public Laws 105–33, 106–113, and 106–554 that are applicable to three classes of these hospitals are implemented, as discussed below.

Various sections of Public Laws 105–33, 106–113, and 106–554 provide for the transition of rehabilitation hospitals and units, psychiatric hospitals and units, and long-term care hospitals from being paid on an excluded hospital basis to being paid on an individual prospective payment system basis. These provisions are as follows:

• Rehabilitation Hospitals and Units. Section 1886(j) of the Act, as added by section 4421 of Public Law 105–33 and amended by section 125 of Public Law 106–113 and section 305 of Public Law 106–554, authorizes the implementation of a prospective payment system for inpatient hospital services furnished by rehabilitation hospitals and units. Section 4421 of Public Law 105–33 amended the Act by adding section 1886(j). Section 1886(j) of the Act provides for a fully implemented prospective payment system for inpatient rehabilitation hospitals and rehabilitation units, effective for cost reporting periods beginning during or after October 2002, with payment provisions during a transitional period based on target amounts specified in section 1886(b) of the Act. Section 125 of Public Law 106–113 amended section 1886(j) of the Act to require the Secretary to use a discharge as the payment unit for inpatient rehabilitation services under the prospective payment system and to establish classes of patient discharges by functional-related groups. Section 305 of Public Law 106–554 further amended section 1886(j) of the Act to allow hospitals to elect to be paid the full Federal prospective payment rather than the transitional period payments specified in the Act. A final rule implementing the prospective payment system for inpatient rehabilitation hospitals will be published in the **Federal Register** shortly.

• Psychiatric Hospitals and Units. Sections 124(a) and (c) of Public Law 106–113 provide for the development of a per diem prospective payment system for payment for inpatient hospital services of psychiatric hospitals and units under the Medicare program, effective for cost reporting periods beginning on or after October 1, 2002. This system must include an adequate patient classification system that reflects the differences in patient resource use and costs among these hospitals and must maintain budget neutrality. We are in the process of developing a proposed rule, to be followed by a final rule, to implement the prospective payment system for psychiatric hospitals and units, effective for October 1, 2002.

• Long-Term Care Hospitals. Sections 123(a) and (c) of Public Law 106–113 provide for the development of a per discharge prospective payment system for payment for inpatient hospital services furnished by long-term care hospitals under the Medicare program, effective for cost reporting periods beginning on or after October 1, 2002. Section 307(b)(1) of Public Law 106–554 provides that payments under the long-term care prospective payment system will be made on a prospective payment basis rather than a cost basis. The long-term care hospital prospective payment system must include a patient classification system that reflects the differences in patient resource use and costs, and must maintain budget neutrality. We are planning to develop a proposed rule, to be followed by a final rule, to implement the prospective payment system for long-term care hospitals, effective for October 1, 2002. Section 307 of Public Law 106–554 provides that if the Secretary is unable to develop a prospective payment system for long-term care hospitals that can be implemented by October 1, 2002, the Secretary must implement a prospective payment system that bases payment under the system using the existing acute hospital DRGs, modified where feasible to account for resource use of long-term care hospital patients using the most recently available hospital discharge data for long-term care services.

Under sections 1820 and 1834(g) of the Act, payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services on a reasonable cost basis. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under Parts 413 and 415.

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act; the amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year.

The regulations governing the acute care hospital inpatient prospective payment system are located in 42 CFR part 412. The regulations governing excluded hospitals and hospital units are located in Parts 412 and 413. The regulations governing GME payments are located in Part 413. The regulations governing CAHs are located in Parts 413 and 485.

This final rule implements amendments enacted by Public Law 106–554 relating to updates to FY 2002 payments for hospital inpatient services, hospitals' geographic reclassifications and wage indexes, GME costs, the payment adjustment for disproportionate share hospitals (DSHs), the indirect medical education (IME) adjustment for teaching hospitals, and CAHs. It also implements other changes affecting DRG classifications and relative weights, annual updates to the data used to calculate the wage index, sole community hospitals (SCHs), payments under the inpatient capital prospective payment system, and policies related to hospitals and units excluded from the prospective payment system. These changes are addressed in sections II., III., IV., and VI. of this preamble.

Section 533 of Public Law 106–554 requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies by October 1, 2001. We proposed a mechanism in the May 4, 2001 proposed rule. We received 61 comments on our proposed criteria to qualify for this special payment and on the proposed mechanism to pay for qualifying new technologies. Due to this large number of comments, we will publish a separate final rule to respond to comments received on our proposal, and to establish a mechanism, by October 1, 2001.

Although we intend to establish the mechanism by October 1, 2001, we will not make additional payments under the mechanism for cases involving new technology during FY 2002 because it is not feasible. This is due to the timing of the enactment of Public Law 106–554 on December 21, 2000, the requirement that we establish the mechanism through notice and an opportunity for public comment, and the requirement that the payments be implemented in a budget neutral manner. That is, it was not feasible to establish the criteria by which new technologies would qualify through a proposed rule with opportunity for public comment as part of the May 4, 2001 proposed rule, finalize those criteria in response to public comments, allow technologies to qualify under those criteria, and implement payments for any qualified technologies in a budget neutral manner. This is because making the special payments in a budget neutral manner requires an adjustment to the standardized amounts (which must be published in final by August 1 each year).

Representatives of new technologies seeking to qualify for special payments under this provision for FY 2003 should proceed with their application by contacting us at the telephone numbers listed in the ''For Further Information Contact'' section of this preamble. As indicated previously, a final rule containing the specific qualifying criteria and payment mechanism will be published shortly.

This final rule also responds to public comments on, and finalizes implementation of, provisions of Public Law 106–113 that relate to Medicare payments to hospitals for FY 2001 that were addressed in a separate interim final rule with comment period (HCFA–1131–IFC), published in the **Federal Register** on August 1, 2000 (65 FR 47026).

Lastly, this final rule responds to public comments on, and finalizes implementation of, other provisions of Public Law 106–554 that relate to Medicare payments to hospitals effective prior to October 1, 2001 (that is, for FY 2001 or for the period between April l, 2001 and September 30, 2001) that were addressed in a separate interim final rule with comment period (HCFA–1178–IFC), published in the **Federal Register** on June 13, 2001 (66 FR 32172).

In summary, this final rule responds to public comments on, and finalizes, three documents published in the **Federal Register:** The August 1, 2000 interim final rule with comment period, the May 4, 2001 proposed rule (HCFA–1158–P), and the June 13, 2001 interim final rule with comment period, as discussed below.

The charts below specify the effective dates of the various provisions of Public Law 106–113 and Public Law 106–554.

EFFECTIVE DATES OF THE PROVISIONS OF PUBLIC LAW 106–113 INCLUDED IN THIS FINAL RULE

Section No.	Title	Effective date
111	Indirect Medical Education Adjustment Formula	10/01/1999.
121	Wage Adjustment to Caps on Target Amounts for Excluded Hospitals and Units.	10/01/1999.
152(a)	Reclassified Hospitals in Certain Designated Counties	10/01/1999.
153	Calculation of Wage Index for Hattiesburg, Mississippi	10/01/1999.
154	Calculation of Wage Index for Allentown-Bethlehem-Easton, Pennsylvania MSA.	10/01/1999.
312	Initial Residency Period for Child Neurology Residency Programs.	7/01/2000, for residency programs that began before, on, or after 11/29/1999.
401(a)	Reclassification of Certain Urban Hospitals to Rural	01/01/2000.
401(b)(2)	Application of Reclassifications under Section 401(a) to Critical Access Hospitals.	01/01/2000.
403(a)	Length of Stay Restrictions on Inpatient Stays in Critical Access Hospitals.	11/29/1999.
403(b)	Qualifications of For-Profit Hospitals for Critical Access Hospital Status.	11/29/1999.
403(c)	Qualification of Closed Hospitals or Hospitals Downsized to Health Clinics for Critical Access Hospital Designation.	11/29/1999 for hospitals that closed after 11/29/1989; 11/29/1999 for hospitals that downsized to health clinics.
403(e)	Elimination of Medicare Part B Deductible and Coinsurance for Clinical Diagnostic Laboratory Tests Furnished in Critical Access Hospitals.	11/29/1999.
403(f)	Provisions on Swing-Beds in Critical Access Hospitals	11/29/1999.
404	Extension of Medicare-Dependent, Small Rural Hospital Program.	10/01/2002 through 9/30/2006.
407(a)	Residents on Approved Leaves of Absence—GME and IME.	11/29/1999.
407(b)	Expansion of Number of Unweighted Residents in Rural Hospitals—GME and IME.	04/01/2000.
407(c)	Urban Hospitals with Rural Training Tracks or Integrated Rural Tracks—GME and IME.	04/01/2000.
407(d)	Residents Training at Certain Veterans Hospitals—GME and IME.	10/01/1997
408(a)	Swing Beds for Skilled Nursing Facility Level of Care Patients.	07/01/1998 through the end of the facility's third cost reporting period after this date.
408(b)	Elimination of Constraints on Length of Stay in Swing Beds in Rural Hospitals.	07/01/1998 through the end of the facility's third cost reporting period after this date.
541	Additional Payments to Hospitals for Approved Nursing and Allied Health Education to Reflect Utilization of Medicare+Choice Enrollees.	01/01/2000.

EFFECTIVE DATES OF THE PROVISIONS OF PUBLIC LAW 106–113 INCLUDED IN THIS FINAL RULE

Section No.	Title	Effective date
201	Clarification of No Beneficiary Cost-Sharing for Clinical Diagnostic Laboratory Tests Furnished by Critical Access Hospitals.	11/29/1999.
202	Assistance with Fee Schedule Payment for Professional Services under All-Inclusive Rate.	07/01/2001.
211	Threshold for Disproportionate Share Hospitals	04/01/2001.

EFFECTIVE DATES OF THE PROVISIONS OF PUBLIC LAW 106–113 INCLUDED IN THIS FINAL RULE—Continued

Section No.	Title	Effective date
212	Option to Base Eligibility for Medicare-Dependent, Small Rural Hospital Program on Discharges during Two of the Three Most Recently Audited Cost Reporting Periods.	04/01/2001.
213	Extension of Option to use Rebased Target Amounts to All Sole Community Hospitals.	10/01/2000.
301	Revision of Acute Care Hospital Payment Update for 2001	04/01/2001.
302	Additional Modification in Transition for Indirect Medical Education Adjustment.	04/01/2001.
303	Decrease in Reductions for Disproportionate Share Hospitals	04/01/2001.
304(a)	Three-Year Wage Index Reclassifications; Use of 3 Years of Wage Data for Evaluating Reclassifications.	10/01/2001.
304(b)	Statewide Wage Index for Reclassifications	10/01/2001 for reclassification beginning 10/01/2002.
304(c)	Collection of Occupational Case Mix Data	09/30/2003 for application 10/1/2004.
306	Payment for Inpatient Services of Psychiatric Hospitals	10/01/2000.
307	Payment for Inpatient Services of Long-Term Care Hospitals	10/01/2000.
511	Increase in Floor for Payments for Direct Costs of Graduate Medical Education.	10/01/2001.
512	Change in Distribution Formula for Medicare+Choice-Related Nursing and Allied Health Education Costs.	01/01/2001.
541	Increase in Reimbursement for Bad Debt	10/01/2000.

B. Summary of the Provisions of the May 4, 2001 Proposed Rule

On May 4, 2001, we published a proposed rule in the **Federal Register** (66 FR 22646) that set forth proposed changes to the Medicare hospital inpatient prospective payment system for operating and capital-related costs for FY 2002. We set forth proposed changes to the amounts and factors used in determining the rates for these costs. In addition, we proposed changes relating to payments for GME costs and payments to excluded hospitals and units, SCHs, and CAHs.

The following is a summary of the major changes that we proposed and the issues we addressed in the May 4, 2001 proposed rule:

1. Changes to the DRG Reclassifications and Recalibrations of Relative Weights

As required by section 1886(d)(4)(C) of the Act, we proposed annual adjustments to the DRG classifications and relative weights. Based on analyses of Medicare claims data, we proposed to establish a number of new DRGs and make changes to the designation of diagnosis and procedure codes under other existing DRGs for FY 2002.

We also addressed the provisions of section 533 of Public Law 106–544 regarding development of a mechanism for increased payment for new medical services and technologies and the required report to Congress on expeditiously introducing new medical services and technology into the DRGs.

2. Changes to the Hospital Wage Index

We proposed to use wage data taken from hospitals' FY 1998 cost reports in the calculation of the FY 2002 wage index. We also proposed to implement the third year of the phaseout of wage costs related to GME or Part A certified registered nurse anesthetists (CRNA) from the FY 2002 wage index calculation.

We proposed several changes to the wage index methodology that would apply in calculating the FY 2003 wage index, and addressed new procedures for requesting wage data corrections and a modification of the process and timetable for updating the wage index.

- We also discussed the collection of hospital occupational mix data as required by section 304(c) of Public Law 106–554.
- In addition, we discussed revisions to the wage index based on hospital redesignations and reclassifications for purposes of the wage index, including changes to reflect the provisions of sections 304(a) and (b) of Public Law 106–554 relating to 3-year wage index reclassifications by the MGCRB, the use of 3 years of wage data for evaluating reclassification requests for FYs 2003 and later, and the application of a statewide wage index for reclassifications beginning in FY 2003.

3. Other Decisions and Changes to the Prospective Payment System for Inpatient Operating and Graduate Medical Education Costs

We discussed several provisions of the regulations in 42 CFR parts 412 and 413 and set forth certain proposed changes concerning SCHs; rural referral centers; changes relating to the IME adjustment as a result of section 302 of Public Law 106–554; changes relating to the DSH adjustment as a result of section 303 of Public Law 106–554; the establishment of policies relating to the 3-year application of wage index reclassifications by the MGCRB, the use of 3 years of wage data in evaluating reclassification requests to the MGCRB for FYs 2003 and later, and the use of a statewide wage index for reclassifications beginning in FY 2003, as required by sections 304(a) and (b) of Public Law 106–554.

We discussed proposed requirements for qualifying for additional payments for new medical services and technology, as required by section 533(b) of Public Law 106–554.

Lastly, we proposed changes relating to payment for the direct costs of GME, including changes as a result of section 511 of Public Law 106–554.

4. Prospective Payment System for Capital-Related Costs

We proposed payment requirements for capital-related costs, including the special exceptions payment, beginning October 1, 2001.

5. Proposed Changes for Hospitals and Hospital Units Excluded from the Prospective Payment Systems

We discussed the following proposals concerning excluded hospitals and hospital units and CAHs:

- Limits on and adjustments to the proposed target amounts for FY 2002.
- Revision of the methodology for wage neutralizing the hospital-specific target amounts using preclassified wage data.
- Updated caps for new excluded hospitals and units as well as changes

in the effective date of classifications of excluded hospitals and units.

• The prospective payment system for inpatient rehabilitation hospitals and units.

• Payments to CAHs, including exclusion from the payment window requirements; the availability of CRNA pass-through payments; payment for emergency room on-call physicians; treatment of ambulance services; the use of certain qualified practitioners for preanesthesia and postanesthesia evaluations; and clarification of location requirements for CAHs.

6. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits

In the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the FY 2002 prospective payment rates for operating costs and capital-related costs. We also proposed threshold amounts for outlier cases. In addition, we proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2002 for hospitals and hospital units excluded from the prospective payment system.

7. Impact Analysis

In Appendix A, we set forth an analysis of the impact of the proposed changes on affected entities.

8. Capital Acquisition Model

In Appendix B of the proposed rule, we set forth the technical appendix on the proposed FY 2002 capital cost model.

9. Report to Congress on the Update Factor for Hospitals under the Prospective Payment System and Hospitals and Units Excluded From the Prospective Payment System

In Appendix C of the proposed rule, as required by section 1886(e)(3) of the Act, we set forth our report to Congress on our initial estimate of a recommended update factor for FY 2002 for payments to hospitals included in the prospective payment systems, and hospitals excluded from the prospective payment systems.

10. Recommendation of Update Factor for Hospital Inpatient Operating Costs

In Appendix D, as required by sections 1886(e)(4) and (e)(5) of the Act, we included our recommendation of the appropriate percentage change for FY 2002 for the following:

• Large urban area and other area average standardized amounts (and hospital-specific rates applicable to SCHs and Medicare-dependent, small rural hospitals) for hospital inpatient services paid for under the prospective payment system for operating costs.

• Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by hospitals and hospital units excluded from the prospective payment system.

11. Discussion of Medicare Payment Advisory Commission Recommendations

In the proposed rule, we discussed recommendations by the Medicare Payment Advisory Commission (MedPAC) concerning hospital inpatient payment policies and presented our responses to those recommendations. Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, not later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. We respond to those recommendations in section VII. of this preamble. For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 653–7220 or visit MedPAC's website at: *www.medpac.gov.*

12. Public Comments Received in Response to the May 4, 2001 Proposed Rule

We received a total of 232 timely items of correspondence containing multiple comments on the proposed rule. Major issues addressed by the commenters included: additional payments for new medical services and technologies, geographic reclassifications of hospitals for purposes of the wage index, DRG reclassifications, payments for GME, and payments to CAHs.

Summaries of the public comments received and our responses to those comments are set forth below under the appropriate heading, with the exception of comments and responses pertaining to specific payments for new technologies under section 533 of Public Law 106–554. As described previously, this provision will be implemented through a separate final rule.

C. Summary of the Provisions of the August 1, 2000 Interim Final Rule with Comment Period

On August 1, 2000, we published in the **Federal Register** (65 FR 47026) an interim final rule with comment period that implemented, or conformed the regulations to, certain statutory provisions relating to Medicare payments to hospitals for inpatient services that were contained in Public Law 106–113, that were effective for FY 2000. The following is a summary of the policy changes we implemented as a result of Public Law 106–113:

1. Changes Relating to Payments for Operating Costs Under the Hospital Inpatient Prospective Payment System

• *Reclassification of Certain Counties.* We implemented the provisions of section 152(a) of Public Law 106–113 that reclassified hospitals in certain designated counties for purposes of making payments to affected hospitals under section 1886(d) of the Act for FY 2000. The counties affected by this provision are identified under section III. of this preamble.

• *Wage Index.* We implemented sections 153 and 154 of Public Law 106–113 that contain provisions affecting the wage indexes of specific Metropolitan Statistical Areas (MSA). Under section 153, the Hattiesburg, Mississippi FY 2000 wage index was calculated including wage data from Wesley Medical Center. Under section 154, the Allentown-Bethlehem-Easton, Pennsylvania MSA FY 2000 wage index was calculated including wage data for Lehigh Valley Hospital.

• *Reclassification of Certain Urban Hospitals as Rural Hospitals.* We implemented section 401 of Public Law 106–113 which directed the Secretary to treat certain hospitals located in urban areas as being located in rural areas of their State if the hospital meets statutory criteria and files an application with HCFA. This provision was effective on January 1, 2000.

• *IME Adjustment.* We implemented section 111 of Public Law 106–113 which provided for an additional payment to teaching hospitals equal to the additional amount the hospitals would have been paid for FY 2000 if the IME adjustment formula (which reflects the higher indirect operating costs associated with GME) for FY 2000 had remained the same as for FY 1999.

• *Extension of the MDH Provision.* We implemented section 404 of Public Law 106–113 which extended the MDH program and its current payment methodology for an additional 5 years, from FY 2002 through FY 2006.

2. Additional Changes Relating to Direct GME and IME

• *Initial Residency Period for Child Neurology Residency Programs.* We implemented section 312 of Public Law 106–113 which provides that in determining the number of residents for purposes of GME and IME payments, the period of board eligibility and the initial residency period for child neurology is the period of board

eligibility for pediatrics plus 2 years. This provision is effective on or after July 1, 2000, for residency programs that began before, on, or after November 29, 1999.

• *Residents on Approved Leaves of Absence.* We implemented section 407(a) of Public Law 106–113 which provides that, for purposes of determining a hospital's full-time equivalent (FTE) cap for direct GME payments and the IME adjustment, a hospital may count an individual to the extent that the individual would have been counted as a primary care resident for purposes of the FTE cap but for the fact that the individual was on maternity or disability leave or a similar approved leave of absence. The provision relating to direct GME was effective with cost reporting periods beginning on or after November 29, 1999. The provision relating to the IME adjustment applied to discharges occurring in cost reporting periods beginning on or after November 29, 1999.

• *Expansion of Number of Unweighted Residents in Rural Hospitals.* We implemented section 407(b) of Public Law 106–113 which provides that a rural hospital's resident FTE count for direct GME and IME may not exceed 130 percent of the number of unweighted residents that the rural hospital counted in its most recent cost reporting period ending on or before December 31, 1996. The provision relating to direct GME applied to cost reporting periods beginning on or after April 1, 2000. The provision relating to the IME adjustment applied to discharges occurring on or after April 1, 2000.

• *Urban Hospitals with Rural Training Tracks or Integrated Rural Tracks.* We implemented section 407(c) of Public Law 106–113 which allows an urban hospital that establishes separately accredited approved medical residency training programs (or rural training tracks) in a rural area or has an accredited training program with an integrated rural track to receive an FTE cap adjustment for purposes of direct GME and IME. The provision was effective with cost reporting periods beginning on or after April 1, 2000, for direct GME, and with discharges occurring on or after April 1, 2000, for IME.

• *Residents Training at Certain Veterans Affairs Hospitals.* We implemented section 407(d) of PublicLaw 106–113 which provides that a non-Veterans Affairs (VA) hospital may receive a temporary adjustment to its FTE cap to reflect residents who were training at a VA hospital and were transferred on or after January 1, 1997, and before July 31, 1998, to the non-VA hospital because the program at the VA hospital would lose its accreditation by the Accreditation Council on Graduate Medical Education if the residents continued to train at the facility. This provision applies as if it was included in the enactment of Public Law 105–33, that is, for direct GME, with cost reporting periods beginning on or after October 1, 1997, and for IME, for discharges occurring on or after October 1, 1997. If a hospital is owed payments as a result of this provision, payments must be made immediately.

3. Payments for Nursing and Allied Health Education: Utilization of Medicare+Choice Enrollees

We implemented section 541 of Public Law 106–113 which provides an additional payment to hospitals that receive payments under section 1861(v) of the Act for approved nursing and allied health education programs associated with services to Medicare+Choice enrollees. This provision is effective for portions of cost reporting periods occurring on or after January 1, 2000.

4. Changes Relating to Hospitals and Hospital Units Excluded From the Prospective Payment System

We implemented section 121 of Public Law 106–113 which amended section 1886(b)(3)(H) of the Act to direct the Secretary to provide for an appropriate wage adjustment to the caps on the target amounts for psychiatric hospitals and units, rehabilitation hospitals and units, and long-term care hospitals for cost reporting periods beginning on or after October 1, 1999.

5. Changes Relating to CAHs

We implemented—

• Section 401(b) of Public Law 106–113, which contained conforming changes to incorporate the reclassifications made by section 401(a) of Public Law 106–113 to the CAH statute (section 1820(c)(2)(B)(i) of the Act). This provision is effective beginning on January 1, 2000.

• Section 403(a) of Public Law 106–113, which deleted the 96-hour length of stay restriction on inpatient care in a CAH and authorized a period of stay that does not exceed, on an annual, average basis, 96 hours per patient. This provision is effective beginning on November 29, 1999.

• Section 403(b) of Public Law 106–113, which allows for-profit hospitals to qualify for CAH status. This provision is effective beginning on November 29, 1999.

• Section 403(c) of Public Law 106–113, which allows hospitals that have closed within 10 years prior to November 29, 1999, or hospitals that downsized to a health clinic or health center, to be designated as CAHs if they satisfy the established criteria for designation, other than the requirement for existing hospital status.

• Section 403(e) of Public Law 106–113, which eliminated the Medicare Part B deductible and coinsurance for clinical diagnostic laboratory tests furnished by a CAH on an outpatient basis. This provision is effective with respect to services furnished on or afterNovember 29, 1999.

• Section 403(f) of Public Law 106–113, entitled ''Participation in Swing Bed Program,'' which amended sections 1883(a)(1) and (c) of the Act.

6. Changes Relating Hospital to Swing Bed Program

We implemented section 408(a) of Public Law 106–113 which eliminated the requirement for a hospital to obtain a certification of need to use acute care beds as swing beds for skilled nursing facility (SNF) level of care patients; and section 408(b) of Public Law 106–113 which eliminates constraints on the length of stay in swing beds for rural hospitals with 50 to 100 beds. These provisions were effective on the first day after the expiration of the transition period for prospective payments for covered SNF services under the Medicare program (that is, at the end of the transition period for the SNF prospective payments system that began with the facility's first cost reporting period beginning on or after July 1, 1998 and extend through the end of the facility's third cost reporting period after this date).

We received a total of eight timely items of correspondence containing multiple comments on the August 1, 2000 interim final rule with comment period. Summaries of the public comments received and our responses to those comments are set forth below under the appropriate section headings of this final rule.

D. Summary of the Provisions of the June 13, 2001 Interim Final Rule With Comment Period

On June 13, 2001, we published an interim final rule with comment period in the **Federal Register** (66 FR 32172) that implemented changes to the Act affecting Medicare payments to hospitals for inpatient services that were made by Public Law 106–554. Some of these changes were effective before the December 21, 2000 date of enactment of Public Law 106–554, on April 1, 2001,

or on July 1, 2001. The changes, on which we requested public comment, are as follows:

1. Changes Relating to Payments for Operating Costs Under the Hospital Inpatient Prospective Payment System

• *Treatment of Rural and Small Urban Disproportionate Share Hospitals (DSHs)* . We implemented the provisions of section 211 of Public Law 106–554 which lowered thresholds by which certain classes of hospitals qualify for DSH payments, with respect to discharges occurring on or after April 1, 2001.

• *Decrease in Reductions for DSH Payments*. We implemented section 303 of Public Law 106–554 which modified the previous reduction in the DSH payment to be 2 percent in FY 2001 and 3 percent in FY 2002.

• *Medicare-Dependent, Small Rural Hospitals (MDHs)*. We implemented section 212 of Public Law 106–554 which provided an option to base eligibility for MDH status on discharges during two of the three most recently audited cost reporting periods, effective with cost reporting periods beginning on or after April 1, 2001.

• *Revision of Prospective Payment System Standardized Amounts.* We implemented section 301 of Public Law 106–554 which revised the update factor increase for the inpatient prospective payment rates for FY 2001.

• *Indirect Medical Education Adjustment (IME).* We implemented section 302 of Public Law 106–554 which provided that for the purposes of making the IME payment for discharges occurring on or after April 1, 2001 and before October 1, 2001, the adjustment will be determined as if the adjustment equaled a 6.75 percent increase in payment for every 10 percent increase in the resident-to-bed ratio, rather than a 6.25 percent increase.

• *SCHs*. We implemented section 213 of Public Law 106–554 which further extended the 1996 rebasing option, for hospital cost reporting periods beginning October 1, 2000, to all SCHs and provides that this extension is effective as if it had been included in section 405 of Public Law 106–113.

2. Payments for Nursing and Allied Health Education: Utilization of Medicare+Choice Enrollees

We implemented section 512 of Public Law 106–554 which revised the formula for determining the additional payment amounts to hospitals for Medicare+Choice nursing and allied health education costs to specifically account for each hospital's Medicare+Choice utilization.

3. Changes Relating to Payments for Capital-Related Costs Under the Hospital Inpatient Prospective Payment System

As a result of implementing section 301 of Public Law 106–554, which provided increased inpatient operating payment rates, we recalculated the unified outlier threshold for inpatient operating and inpatient capital-related costs. Therefore, we revised the capital outlier offset which also required us to revise the capital-related rates.

4. Changes Relating to Hospitals and Hospital Units Excluded From the Prospective Payment System

• *Increase in the Incentive Payment for Excluded Psychiatric Hospitals and Units*. We implemented section 306 of Public Law 106–554, which provided that for cost reporting periods beginning on or after October 1, 2000, for psychiatric hospitals and units, if the allowable net inpatient operating costs do not exceed the hospital's ceiling, payment is the lower of: (1) net inpatient operating costs plus 15 percent of the difference between inpatient operating costs and the ceiling; or, (2) net inpatient costs plus 3 percent of the ceiling.

• *Increase in the Wage Adjusted 75th Percentile Cap on the Target Amounts for Long-Term Care Hospitals*. We implemented section 307(a) of Public Law 106–554, which provided a 2-percent increase to the wage-adjusted 75th percentile cap on the target amount for long-term care hospitals, effective for cost reporting periods beginning during FY 2001.

• *Increase in the Target Amounts for Long-Term Care Hospitals*. We implemented section 307(a) Public Law 106–554, which provided a 25 percent increase to the target amounts for long-term care hospitals for cost reporting periods beginning in FY 2001, up to the cap on target amounts.

5. Changes Relating to CAHs

• *Elimination of Coinsurance for Clinical Diagnostic Laboratory Tests Furnished by a CAH*. We implemented section 201(a) of Public Law 106–554, which amended section 1834(g) of the Act to state that there will be no collection of coinsurance, deductible, copayments, or any other type of cost sharing from Medicare beneficiaries with respect to outpatient clinical diagnostic laboratory services furnished as outpatient CAH services and that those services will be paid for on a reasonable cost basis.

• *Assistance with Fee Schedule Payment for Professional Services under All-Inclusive Rate*. We implemented section 202 of Public Law 106–554, which amended section 1834(g)(2)(B) of the Act to provide that when a CAH elects to be paid for Medicare outpatient services under the reasonable costs for facility services plus fee schedule amounts for professional services method, Medicare will pay 115 percent of the amount it otherwise pays for the professional services.

• *Condition of Participation with Hospital Requirements at the Time of Application for CAH Designation (§ 485.612)*. We implemented a conforming change to correct § 485.612 to reflect that certain entities are not required to have a provider agreement prior to CAH designation.

6. Other Inpatient Costs

• *Increase in Reimbursement for Bad Debts.* We implemented section 541 of Public Law 106–554 which provided a 30 percent decrease of allowable hospital bad debt reimbursement for cost reporting periods beginning during FY 2001 and all subsequent fiscal years. This section modified section 4451 of Public Law 105–33 that reduced the total allowable bad debt reimbursement for hospitals by 45 percent.

We received a total of 13 timely pieces of correspondence containing comments on the June 13, 2001 interim final rule with comment period. A summary of these public comments and our responses to them are set forth under sections IV. and VI. of this final rule.

II. Changes to DRG Classifications and Relative Weights

A. Background

Under the prospective payment system, we pay for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG relative to the average resources used to treat cases in all DRGS.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes

in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Changes to the DRG classification system and the recalibration of the DRG weights for discharges occurring on or after October 1, 2001 are discussed below.

B. DRG Reclassification

1. General

Cases are classified into DRGs for payment under the prospective payment system based on the principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay, as well as age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). Medicare fiscal intermediaries enter the information into their claims processing systems and subject it to a series of automated screens called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before classification into a DRG.

After screening through the MCE and any further development of the claims, cases are classified into the appropriate DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into a DRG on the basis of the diagnosis and procedure codes and demographic information (that is, sex, age, and discharge status). It is used both to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights.

In version 18 of the GROUPER (used for FY 2001), cases are assigned to one of 499 DRGs (including one DRG (469) for a diagnosis that is invalid as a discharge diagnosis and one DRG (470) for ungroupable diagnoses) in 25 major diagnostic categories (MDCs). Most MDCs are based on a particular organ system of the body. For example, MDC 6 is Diseases and Disorders of the Digestive System. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)).

In general, cases are assigned to an MDC, based on the principal diagnosis, before assignment to a DRG. However, there are six DRGs to which cases are directly assigned on the basis of procedure codes. These are the DRGs for heart, liver, bone marrow, and lung transplants (DRGs 103, 480, 481, and 495, respectively) and the two DRGs for tracheostomies (DRGs 482 and 483). Cases are assigned to these DRGs before classification to an MDC.

Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are based on a hierarchy that orders individual procedures or groups of procedures by resource intensity. Medical DRGs generally are differentiated on the basis of diagnosis and age. Some surgical and medical DRGs are further differentiated based on the presence or absence of complications or comorbidities (CC).

Generally, the GROUPER does not consider other procedures. That is, nonsurgical procedures or minor surgical procedures generally not performed in an operating room are not listed as operating room (OR) procedures in the GROUPER decision tables. However, there are a few non-OR procedures that do affect DRG assignment for certain principal diagnoses, such as extracorporeal shock wave lithotripsy for patients with a principal diagnosis of urinary stones.

We proposed numerous changes to the DRG classification system for FY 2002. The proposed changes, the public comments we received concerning them, and the final DRG changes are set forth below. Unless otherwise noted, the changes we are implementing will be effective in the revised GROUPER software (Version 19.0) to be implemented for discharges on or after October 1, 2001. Unless noted otherwise, we are relying on the data analysis in the proposed rule for the changes discussed here.

Chart 1 lists the changes we are making by adding new DRGs or removing old DRGs. Chart 2 summarizes the changes we are making with respect to the reassignment of procedure codes. Chart 3 presents the changes we are making to the titles of existing DRGs.

In Chart 2 of the proposed rule, several procedure codes were erroneously included in the ''Removed from DRG'' column of the chart (66 FR 22650). The 11 affected codes are 37.21, 37.22, 37.23, 37.26, 88.52, 88.53, 88.54, 88.55, 88.56, 88.57, and 88.58. Inclusion of these codes in this chart made it appear as if the codes were being deleted from DRG 104. In fact, they are being additionally assigned to DRG 514. We have corrected Chart 2 in this final rule.

CHART 1.—SUMMARY OF CHANGES IN DRG ASSIGNMENTS

Diagnosis related groups (DRGs)	Added as new	Removed
Pre-MDC:		
DRG 512 (Simultaneous Pancreas/Kidney Transplant)	X	
DRG 513 (Pancreas Transplants)	X	
MDC 5 (Diseases and Disorders of the Circulatory System):		
DRG 112 (Percutaneous Cardiovascular Procedures)		X
DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization)	X	
DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization)	X	
DRG 516 (Percutaneous Cardiovascular Procedures with Acute Myocardial Infarction (AMI))	X	
DRG 517 (Percutaneous Cardiovascular Procedures without AMI, with Coronary Artery Stent Implant	X	
DRG 518 (Percutaneous Cardiovascular Procedures without AMI, without Coronary Artery Stent Implant	X	
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue):		
DRG 519 (Cervical Spinal Fusion with CC)	X	
DRG 520 (Cervical Spinal Fusion without CC)	X	
MDC 20 (Alcohol/Drug Use and Alcohol/Drug-Induced Organic Mental Disorders):		
DRG 434 (Alcohol/Drug Abuse or Dependency, Detoxification or Other Symptomatic Treatment with CC)		X
DRG 435 (Alcohol/Drug Abuse or Dependency, Detoxification or Other Symptomatic Treatment without CC)		X
DRG 436 (Alcohol/Drug Dependence with Rehabilitation Therapy)		X
DRG 437 (Alcohol/Drug Dependence, Combined Rehabilitation and Detoxification Therapy)		X
DRG 521 (Alcohol/Drug Abuse or Dependence with CC)	X	

CHART 1.—SUMMARY OF CHANGES IN DRG ASSIGNMENTS—Continued

Diagnosis related groups (DRGs)	Added as new	Removed
DRG 522 (Alcohol/Drug Abuse or Dependence without CC, with Rehabilitation Therapy)	X	
DRG 523 (Alcohol/Drug Abuse or Dependence without CC, without Rehabilitation Therapy)	X	

CHART 2.—SUMMARY OF ASSIGNMENT OR REASSIGNMENT OF DIAGNOSIS OR PROCEDURE CODES IN EXISTING DRGS

Diagnosis/procedure codes	Removed from DRG	Reassigned to DRG
MDC 5 (Diseases and Disorders of the CirculatorySystem)		
Principal Diagnosis Code:		
410.01 Acute myocardial infarction of anterolateral wall, initial episode of care	116	516.
410.11 Acute myocardial infarction of other anterior wall, initial episode of care	116	516.
410.21 Acute myocardial infarction of inferolateral wall, initial episode of care	116	516.
410.31 Acute myocardial infarction of inferoposterior wall, initial episode of care	116	516.
410.41 Acute myocardial infarction of other inferior wall, initial episode of care	116	516.
410.51 Acute myocardial infarction of other lateral wall, initial episode of care	116	516.
410.61 True posterior wall infarction, initial episode of care	116	516.
410.71 Subendocardial infarction, initial episode of care	116	516.
410.81 Acute myocardial infarction of other specified sites, initial episode of care	116	516.
410.91 Acute myocardial infarction of unspecified site, initial episode of care	116	516
Procedure Codes:		
37.94 Implantation or replacement of automatic cardioverter/defibrillation, total system (AICD)	104, 105	514, 515.
37.95 Implantation of automatic cardioverter/defibrillator lead(s) only	104, 105	514, 515.
37.96 Implantation of automatic cardioverter/defibrillator pulse generator only	104, 105	514, 515.
37.97 Raplacement of automatic cardioverter/defibrilator lead(s) only;	104, 105	514, 515.
37.98 Replacement of automatic cardioverter/defibrillator pulse generator only	104, 105	514, 515.
Operating Room Procedures:		
35.96 Percutaneous valvuloplasty	112, 116	516, 517, 518.
36.01 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy without mention of thrombolytic agent.	112, 116	516, 517, 518.
36.02 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy with mention of thrombolytic agent.	112, 116	516, 517, 518.
36.05 Multiple vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent.	112, 116	516, 517, 518.
36.09 Other removal of coronary artery obstruction	112, 116	516, 517, 518.
37.34 Catheter ablation of lesion or tissues of heart	112, 116	516, 517, 518.
92.27 Implantation or insertion of radioactive elements	non-OR in MDC–5	517
Nonoperating Room Procedures:		
36.06 Insertion of coronary artery stent(s)	116	517.
37.26 Cardiac electrophysiologic stimulation and recording studies	112	514, 516, 517, 518.
37.27 Cardiac mapping	112	516, 517, 518.
MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)		
Procedure Codes:		
81.02 Other cervical fusion, anterior technique	497, 498	519, 520.
81.03 Other cervical fusion, posterior technique	497, 498	519, 520.
MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period)		
Diagnosis Codes:		
770.7 Chronic respiratory disease arising in the perinatal period	387, 389	92, 93.
773.0 Hemolytic disease due to RH isoimmunization	387, 389	390.
773.1 Hemolytic disease due to ABO isoimmunization	387, 389	390.
Secondary Diagnosis Codes:		
478.1 Other diseases of nasal cavity and sinuses	390	391.
520.6 Disturbances in tooth eruption	390	391.
623.8 Other specified noninflammatory disorders of vagina	390	391.
709.00 Dyschromia, unspecified	390	391.
709.01 Vitiglio	390	391.
709.09 Dyschromia, Other	390	391.
744.1 Accessory Auricle	390	391.
754.61 Congenital pes planus	390	391.
757.33 Congenital pigmentary anomalies of skin	390	391.
757.39 Other specified anomaly of skin	390	391.
764.08 ''Light for dates'' without mention of fetal malnutrition, 2,000–2,499 grams	390	391.
764.98 Fetal growth retardation, unspecified, 2,000–2,499 grams	390	391.
772.6 Cutaneous hemorrhage	390	391.
779.3 Feeding problems in newborns	390	391
794.15 Abnormal and auditory function studies	390	391.

CHART 2.—SUMMARY OF ASSIGNMENT OR REASSIGNMENT OF DIAGNOSIS OR PROCEDURE CODES IN EXISTING DRGS—Continued

Diagnosis/procedure codes	Removed from DRG	Reassigned to DRG
796.4 Other abnormal clinical findings	390	391.
V20.2 Routine infant or child health check	390	391.
V72.1 Examination of ears and hearing	390	391.

CHART 3.—SUMMARY OF RETITLED DRGS

MDC	DRG No.	Current name	New name
MDC 5	DRG 116	Other Permanent Cardiac Pacemaker Implantation, or PTCA, with Coronary Artery Stent Implant.	Other Cardiac Pacemaker Implantation.
MDC 8	DRG 497	Spinal Fusion with CC	Spinal Fusion except Cervical with CC.
MDC 8	DRG 498	Spinal Fusion without CC	Spinal Fusion except Cervical with CC.

2. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Removal of Defibrillator Cases from DRGs 104 and 105

DRGs 104 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization) and 105 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization) include the replacement or open repair of one or more of the four heart valves. These valves may be diseased or damaged, resulting in either leakage or restriction of blood flow to the heart, compromising the ability of the heart to pump blood. This procedure requires the use of a heart-lung bypass machine, as the heart must be stilled and opened to repair or replace the valve.

Cardiac defibrillators are implanted to correct episodes of fibrillation (very fast heart rate) caused by malfunction of the conduction mechanism of the heart. Through implanted cardiac leads, the defibrillator mechanism senses changes in heart rhythm. When very fast heart rates occur, the defibrillator produces a burst of electric current through the leads to restore the normal heart rate. An implanted defibrillator constantly monitors heart rhythm. The implantation of this device does not require the use of a heart-lung bypass machine, and would be expected to be very different in terms of resource usage, although both procedures currently group to DRGs 104 and 105.

For the proposed rule, as part of our ongoing review of DRGs, we examined Medicare claims data on DRG 104 and DRG 105. We reviewed 100 percent of the FY 2000 MedPAR file containing hospital bills received through May 31, 2000, for discharges in FY 2000, and found that the average charges across all cases in DRG 104 were $84,060, while the average charges across all cases in DRG 105 were $66,348. Carving out code 37.94 (Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]) from DRGs 104 and 105 increased those average charges to $91,366 for DRG 104 and $67,323 for DRG 105. We identified 11,021 defibrillator cases in DRG 104 (out of 25,112 total cases), with average charges of $74,719, and 2,434 defibrillator cases in DRG 105 (out of 20,094 total cases), with average charges of $59,267.

We performed additional review on cases containing code 37.95 (Implantation of automatic cardioverter/defibrillator lead(s) only) with code 37.96 (Implantation of automatic cardioverter/defibrillator pulse generator only) and on cases containing code 37.97 (Replacement of automatic cardioverter/defibrillator lead(s) only) with code 37.98 (Replacement of automatic cardioverter/defibrillator pulse generator only). This subgrouping contained only 56 patients. The average charges for the 18 patients in DRG 104 were $58,847. The average charges for the 38 patients in DRG 105 were $54,891.

In the proposed rule, because we believed the defibrillator cases are significantly different from other cases in DRGs 104 and 105, we proposed two new DRGs: DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization) and DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization).

We also proposed the removal of procedure codes 37.94, 37.95 and 37.96, and 37.97 and 37.98 from DRGs 104 and 105 to form the new DRGs 514 and 515.

We received 58 comments on this proposal.

Comment: Many commenters noted that implanted cardioverter defibrillators (ICDs) or AICDs are lifesaving devices that demonstrate state-of-the-art technology for the treatment of cardiac arrhythmias by continuously monitoring, analyzing, and, if needed, restoring a patient's normal heart rhythm.

One commenter described the technology. Similar to the size of a pacemaker, the ICD is placed under the skin of the upper chest. It has the capacity to continuously monitor and analyze a patient's heart rhythm. If the ICD detects an arrhythmia, it can terminate the abnormal rhythm with either a pacemaker function or the delivery of a low-energy electrical shock to restore normal heart rhythm.

Response: We agree that ICDs and AICDs are an important addition to the treatment of cardiac disease. The creation of DRGs 514 and 515 is not meant to effect a judgement call about the efficacy or importance of this treatment, but simply to attempt to improve the accuracy of payments within MDC 5, based on the actual charge data associated with these cases.

Comment: A vast majority of the commenters expressed concern that payments associated with defibrillators will decrease for FY 2002 as a result of this change, with some commenters noting that an ICD or AICD may cost the hospital between $22,000 and $25,000 per device. The commenters stated that if this is the case, there is a limited amount for the remainder of the hospital care (for example, operating room, supplies, nursing staff salary, and typically a 7-day stay in an intensive care unit). Most commenters called for

additional analysis prior to implementation of DRGs 514 and 515.

Response: As we described in the proposed rule and above, DRGs 104 and 105 currently include many different procedures, with a range of costs associated with these different procedures. We proposed to change the assignment of cardiac defibrillators to new DRGs 514 and 515 to more accurately pay for the more expensive procedures remaining in DRGs 104 and 105, as well as to improve the payment accuracy for cardiac defibrillators. In fact, the relative weight of DRG 104 increases from FY 2001 to FY 2002 by 9.1 percent.

Comment: Many commenters argued that using hospital charges to determine DRG relative weights can give a distorted picture of the costs of a procedure. The commenters referred to an unspecified national database indicating that the average mark-up of charges over cost for ICDs is lower than the mark-up applied to other components of care. Other commenters referred to the March 2001 Report to Congress by the MedPAC, which, in the context of evaluating available data for setting accurate relative values, stated that hospitals' billed charges ''give a distorted picture of relative costliness across DRGs because they reflect systematic differences among hospitals in the average mark-up of charges over costs'' (page 11).

Several commenters stated that about 66 percent of hospitals are losing $5,000 or more per case for these procedures. These commenters did not understand why payment would be reduced even further in light of those losses.

Response: Hospital charges have been the basis for recalibrating the DRG relative weights since FY 1986 (see 50 FR 24372 and 50 FR 35652). To the extent that the mark-up of charges over costs varies from one particular device or procedure to another, the relative weights will be impacted. However, due to the relativity of the DRG weights, a low mark-up associated with one device or procedure will be offset by relatively higher mark-ups associated with another device or procedure, leading to higher relative weights, and thus higher payments, for the latter device or procedure. The prospective payment system is an average-based payment methodology, where hospitals are expected to offset any losses they may incur from any individual or group of cases with payment gains incurred from other cases.

Furthermore, hospital charges are determined by each hospital on an item-by-item basis. It is not possible to account for these individual management decisions in the process of developing a national payment system based on prospectively determined average payment rates.

As demonstrated in the impact analysis in Appendix A to this final rule, hospital payments would rise (prior to the budget neutrality adjustment) by 0.3 percent as a result of all of the DRG changes we are implementing in this final rule, including this change. In addition, we note that the latest analysis by MedPAC indicates the average hospital Medicare inpatient operating margin during FY 1999 (the latest year available) was 12.0 percent (Report to the Congress: Medicare Payment Policy, page 64). Therefore, we believe that hospitals will be able to adequately adjust to these payment changes in both the short and the long term.

Comment: One commenter noted that the adjustment to DRGs 104 and 105 as reflected in Table 5, ''List of Diagnosis Related Groups (DRGs), Relative Weighting Factors, Geometric and Arithmetic Mean Length of Stay,'' in the Addendum of the proposed rule, does not reflect the resource consumption as discussed above. The commenter recommended that we increase the relative weights to reflect the resource consumption of DRGs 104 and 105.

Response: In this final rule, the relative weight for DRG 104 is 7.8411 for FY 2002, an increase of 9.1 percent from FY 2001. The relative weight for DRG 105 in this final rule is 5.6796 for FY 2002, a 0.4 percent increase from FY 2001. These percentage changes are very similar to the percent change in average charges in DRGs 104 and 105 after removing ICD and AICD charges, as described above. We note that the final relative weight values are based on 100 percent of FY 2000 discharges in the MedPAR database as of March 2001. The analysis using average charges described above was based on an earlier sample of cases; therefore, the percentage changes do not match exactly.

Comment: Other commenters noted that this change, and the resulting increase in payments for procedures remaining in DRGs 104 and 105, is a positive step to improving the payment for heart assist devices. However, the commenters were disappointed that we did not take the opportunity to make a similar revision for cases involving mechanical heart assist devices.

Response: As described above, removing the ICDs/AICDs from DRGs 104 and 105 will have the net effect of increasing the relative weights for both DRGs, so payment for the remaining cases will increase. We will continue to evaluate our options for improving the accuracy of our payments for heart assist technologies.

After carefully reviewing all of the comments submitted, we have decided to proceed with the creation of two new DRGs to capture cases involving the implantation of cardiac defibrillators. The new DRGs 514 and 515 include principal diagnosis codes and procedure codes as reflected in Chart 4 below:

CHART 4.—COMPOSITION OF NEW DRGS 514 AND 515 IN MDC 5

Diagnosis and procedure codes	Included in DRG 514	Included in DRG 515
Principal Diagnosis Codes:		
All of the principal diagnosis codes assigned to MDC–5	X	X
Principal or Secondary Procedure Code:		
37.94 Implantation or replacement of automatic cardioverter/defibrillator, total system (AICD)	X	X
Combination Operating Procedure Codes:		
37.95 Implantation of automatic cardioverter/defibrillator lead(s) only;		
Plus		
37.96 Implantation of automatic cardioverter/defibrillator pulse generator only;	X	X
Or		
37.97 Replacement of automatic cardioverter/defibrillator lead(s) only;		
Plus		
37.98 Replacement of automatic cardioverter/defibrillator pulse generator only	X	X
Plus: One of the Following Nonoperating Room ProcedureCodes:		
37.21 Right heart cardiac catheterization	X	
37.22 Left heart cardiac catheterization	X	

CHART 4.—COMPOSITION OF NEW DRGS 514 AND 515 IN MDC 5—Continued

Diagnosis and procedure codes		Included in DRG 514	Included in DRG 515
37.23	Combined right and left heart cardiac catheterization	X	
37.26	Cardiac electrophysiologic stimulation and recording studies	X	
88.52	Angiocardiography of right heart structures	X	
88.53	Angiocardiography of left heart structures	X	
88.54	Combined right and left heart angiocardiography	X	
88.55	Coronary arteriography using a single catheter	X	
88.56	Coronary arteriography using two catheters	X	
88.57	Other and unspecified coronary arteriography	X	
88.58	Negative-contrast cardiac roentgenography	X	

b. Percutaneous Cardiovascular Procedures

In the May 4 proposed rule, we indicated that we had reviewed other DRGs within MDC 5 in order to determine if there were also logic changes that could be made to these DRGs. The data were arrayed in a variety of ways displaying myriad permutations, resulting in the following proposed changes.

A percutaneous transluminal coronary angioplasty (PTCA) is an acute intervention intended to minimize cardiac damage by restarting circulation to the heart. Some patients with an acute myocardial infarction (AMI) are now treated by performing a PTCA during the hospitalization for the AMI. Currently, PTCAs with a coronary stent implant are assigned to DRG 116 (Other Permanent Cardiac Pacemaker Implantation, or PTCA with Coronary Artery Stent Implant), along with pacemaker implants. The remaining percutaneous cardiovascular procedures are assigned to DRG 112 (Percutaneous Cardiovascular Procedures).

The volume of percutaneous cardiovascular procedures has grown dramatically, with 186,669 cases identified in the FY 2000 MedPAR file containing hospital bills submitted through May 31, 2000. Because of the high volume, we decided to review the DRG for percutaneous cardiovascular procedures. As a first step in the evaluation, we combined the percutaneous cardiovascular procedures from DRGs 112 and 116. We then subdivided the combined percutaneous cardiovascular procedure group into two groups based on the principal diagnosis (Pdx) of AMI.

Group	Count	Average charge
With Pdx of AMI	50,442	$31,722
Without Pdx of AMI	136,227	23,989

Each of these groups was further evaluated by subdividing them based on whether a coronary stent was implanted. The vast majority of patients with an AMI had a coronary stent implanted. Patients without an AMI were subdivided into two groups based on whether a coronary stent was implemented.

Group	Count	Average charge
Without Pdx of AMI with stent	111,441	$24,745
Without Pdx of AMI without stent	24,786	20,589

In the proposed rule, based on this analysis, we proposed the removal of PTCAs with coronary artery stent from DRG 116, thus limiting DRG 116 to permanent cardiac pacemaker implantation. This removal would leave approximately 68,000 non-PTCA cases in DRG 116.

In conjunction with this evaluation, we considered a new technology, intravascular brachytherapy, that is being used to treat coronary in-stent stenosis. A gamma-radiation-impregnated tape is threaded through the affected vessel for a specified amount of dwell time, and then the tape is removed. Intravascular brachytherapy was approved by the Food and Drug Administration in November 2000.

Intravascular brachytherapy is assigned to procedure code 92.27 (Implantation or insert of radioactive elements). With the use of angioplasty, these cases are currently assigned to DRG 112 (Percutaneous Cardiovascular Procedures). Therefore, cases involving this new technology will be implicated by these changes.

Also in the proposed rule, we proposed to retitle DRG 116 ''Other Cardiac Pacemaker Implantation,'' remove DRG 112, and create three new DRGs: DRG 516 (Percutaneous Cardiovascular Procedures with Acute Myocardial Infarction (AMI)); DRG 517 (Percutaneous Cardiovascular Procedures without AMI, with Coronary Artery Stent Implant); and DRG 518 (Percutaneous Cardiovascular Procedures without AMI, without Coronary Artery Stent Implant). In order to be assigned to new DRG 516, cases must contain one of the principal diagnoses *plus* the operating room procedures listed in Chart 5. Because DRG 516 contains acute myocardial infarction, which is hierarchically ordered before DRGs 517 and 518, any AMI cases also containing codes 92.27 or 36.06 (Insertion of coronary artery stents(s)) would automatically be assigned to DRG 516. We also proposed the assignment of patients with a percutaneous cardiovascular procedure and intravascular radiation treatment to new DRG 517. As more data become available, we will reassess the assignment of intravascular radiation treatment to DRG 517. New DRG 518 would contain the same operating room and nonoperating room procedures as new DRG 517, with the exception of codes 92.27 and 36.06. We received 10 comments on this proposal.

Comment: Several commenters supported the reclassification of percutaneous vascular procedures to DRGs within this MDC. Other commenters, however, stated the proposed changes would be inappropriate because they would reduce payment overall for percutaneous cardiovascular procedures. These commenters noted that new technologies associated with these procedures are, in fact, more costly rather than less costly. In addition, commenters expressed concern that payment for pacemakers under DRG 116 would be reduced from FY 2001 levels.

Response: Based on 100 percent of FY 2000 discharges on file through March 2001, we estimate the case-weighted average relative weight for DRGs 116, 516, 517 and 518 to be 2.2236, a 4.5 percent decline from the case-weighted average relative weight for DRGs 112 and 116 for FY 2001 (2.3280). As discussed above in relation to the new DRGs 514 and 515, the calculation of

the relative weights reflects the charges submitted by hospitals for these cases.

Comment: Five commenters addressed only the inclusion of code 92.27 (Implantation or insertion of radioactive elements, also known as brachytherapy) in new DRG 517 in cases without presence of AMI (these cases would go to DRG 516 if AMI were present). Four of the five expressed appreciation for this change, citing its clinical appropriateness and increased payment, which is close to the additional facility costs for performing the procedure.

One commenter, while commending the decision to assign these cases to DRG 517, requested clarification about our decisionmaking process in assigning this technology to the same DRG as coronary stents. The commenter requested that we outline the specific criteria we applied or the process we followed to evaluate the adequacy of the external data submitted.

Response: Although we received external data from a manufacturer of this technology, they were not the basis for our decision, as we were unable to verify the data because the data were submitted too late in the process of preparing the FY 2002 proposed rule. When we proposed to restructure DRGs 112 and 116, our decision was based on the clinical coherence of the DRGs. Intravascular radiation treatment is an invasive procedure that requires an additional 35 to 45 minutes, and requires the services of both a radiation (nuclear) physicist and a radiation safety officer in the operating room, as well as specifically trained operating room personnel, such as an ultrasound specialist.

Comment: One commenter wrote that these changes fail to account for the use of GP IIB–IIIA inhibitors for cases with acute coronary syndromes. The commenter was concerned whether the DRG assignment for these cases under the proposed DRGs would be appropriate.

Response: The administration of GP IIB–IIIA inhibitors is through intravenous infusion, and is assigned to code 99.20 (Injection or infusion of platelet inhibitor). The GROUPER does not recognize code 99.20 as a procedure and, therefore, its presence does not affect DRG assignment. As described above, the DRG assignment for these cases under the newly configured DRGs 116, 516, 517, and 518 would be determined by the presence of AMI and the presence of other procedures that would cause the case to group to one of the other DRGs besides 518. Our analysis of FY 2000 MedPAR data indicates that, among cases with code 99.20 currently assigned to either DRGs 112 or 116 for FY 2000, the majority of these cases are currently assigned to DRG 116 (317,108 discharges compared to 52,945). Therefore, the majority of these cases involve procedures that do affect DRG assignment. We will continue to evaluate these cases, however, to determine whether further revisions would be appropriate.

Comment: One commenter indicated that codes 37.27 (Cardiac mapping) and 37.34 (Catheter ablation of lesion or tissues of heart) would now be grouped to new DRGs 516, 517, and 518. Because these procedures are not usually used on patients with AMI or patients who receive a stent, the commenter indicated the cases would most likely be grouped to DRG 518. The commenter believed that we were unaware that certain procedures, such as the two previously mentioned, have greater resource utilization than other percutaneous cardiovascular procedures that do not involve AMI or stents. The commenter asserted that this is an inadvertently inappropriate classification. The commenter recommended that CMS either create a separate DRG for cardiac mapping and ablation procedures, or else assign codes 37.27 and 37.34 to DRG 516 after retitling the DRG appropriately.

Response: These cases previously were assigned to either DRG 112 or 116, depending upon whether they involved the insertion of a stent or the implantation of a pacemaker. This GROUPER assignment logic did not change, although the presence or absence of AMI is now a factor as well. We believe this is an appropriate clinical categorization. However, we will consider this issue as we continue to evaluate these DRGs.

The principal diagnosis codes and operating room and nonoperating room procedure codes that are included in the new DRGs 516, 517, and 518 are reflected in Chart 5.

CHART 5.—COMPOSITION OF NEW DRGS 516, 517, AND 518 IN MDC 5

Diagnosis and procedure codes	Included in DRG 516	Included in DRG 517	Included in DRG 518
Principal Diagnosis Codes:			
410.01 Acute myocardial infarction of anterolateral wall, initial episode of care	X		
410.11 Acute myocardial infarction of other anterior wall, initial episode of care	X		
410.21 Acute myocardial infarction of inferolateral wall, initial episode of care	X		
410.31 Acute myocardial infarction of inferoposterior wall, initial episode of care	X		
410.41 Acute myocardial infarction of other inferior wall, initial episode of care	X		
410.51 Acute myocardial infarction of other lateral wall, initial episode of care	X		
410.61 True posterior wall infarction, initial episode of care	X		
410.71 Subendocardial infarction, initial episode of care	X		
410.81 Acute myocardial infarction of other specified sites, initial episode of care	X		
410.91 Acute myocardial infarction of unspecified site, initial episode of care	X		
Plus:			
Operating Room Procedures:			
35.96 Percutaneous valvuloplasty	X	X	X
And			
36.01 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy without mention of thrombolytic agent	X	X	X
Or			
36.02 Single vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy with mention of thrombolytic agent	X	X	X
Or			
36.05 Multiple vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent	X	X	X

CHART 5.—COMPOSITION OF NEW DRGS 516, 517, AND 518 IN MDC 5—Continued

Diagnosis and procedure codes	Included in DRG 516	Included in DRG 517	Included in DRG 518
And			
36.09 Other removal of coronary artery obstruction	X	X	X
And			
37.34 Catheter ablation of lesion or tissues of heart	X	X	X
92.27 Implantation or insertion of radioactive elements	.....	X	.....
Or:			
Nonoperating Room Procedures:			
36.06 Insertion of coronary artery stent(s)	.....	X	.....
37.26 Cardiac electrophysiologic stimulation and recording studies	X	X	X
37.27 Cardiac mapping	X	X	X

DRG 121 (Circulatory Disorders with AMI and Major Complication, Discharged Alive), DRG 122 (Circulatory Disorders with AMI without Major Complication, Discharged Alive), and DRG 123 (Circulatory Disorders with AMI, Expired) are not affected by these changes.

c. Removal of Heart Assist Systems

The ICD–9–CM Coordination and Maintenance Committee considered the nonoperative removal of heart assist systems at its November 17, 2000 meeting. A device called the intra-aortic balloon pump (IABP) is one of the most common types of ventricular assist systems. A balloon catheter is placed into the patient's descending thoracic aorta, and inflates and deflates with each heartbeat. This device is timed with the patient's own heart rhythm, and inflates and circulates blood to the heart and other organs. This allows the heart to rest and recover. The IABP may be used preoperatively, intraoperatively, or postoperatively. It supports the patient from a few hours to several days.

Code 37.64 (Removal of heart assist system) already exists, and it is considered by the GROUPER to be an operative procedure. However, the nonoperative removal of a heart assist system can be done at the patient's bedside, is noninvasive, and requires no anesthesia. Therefore, the Committee created code 97.44 (Nonoperative removal of heart assist system) for use with discharges beginning on or after October 1, 2001.

In the past, we have assigned new ICD–9–CM codes to the same DRG to which the predecessor code was assigned. In the proposed rule, we explained that if this practice were to be followed, we would have proposed that code 97.44 be assigned to MDC 5, DRGs 478 (Other Vascular Procedures with CC) and 479 (Other Vascular Procedures without CC). After hospital charge data became available, we would have considered moving it to other DRGs. However, in accordance with section 533(a) of Public Law 106–554, which requires a more expeditious technique of recognizing new medical services or technology for the hospital inpatient prospective payment system, we will reconsider this longstanding practice when possible. Therefore, as code 97.44 was designed to capture heart assist system removal that is clearly nonoperative, we did not propose to designate 97.44 as a code which the GROUPER recognizes as a procedure. The GROUPER will assign these cases to a medical DRG based on the principal diagnosis, or to a surgical DRG if a surgical procedure recognized by the GROUPER is performed. This assignment can be found in Table 6B, New Procedure Codes, in the Addendum to this rule.

We received no comments on this proposal. However, we did receive comments on another issue in MDC 5, relating to DRGs 110 and 111 (Major Cardiovascular Procedures with and without CC).

Comment: One commenter submitted a case study on stent technology, noting that Medicare payments in their facility were 31.4 percent lower than total costs. This commenter made no recommendations, but stated that often surgeons must use additional stent segments to repair aneurysms, increasing total costs by thousands of dollars.

Response: We do not have a clear understanding of the commenter's statement that often surgeons must use additional stent segments to repair aneurysms, thereby increasing total costs. We are unclear because the device presented to us for new ICD–9–CM code consideration was proposed as a single device, custom-fitted to the patient's needs. We will continue to monitor this technology and the new code (used for discharges on or after October 1, 2001).

Comment: One commenter noted that aortic endografts are assigned to DRGs 110 and 111, and the cost of the device alone is greater than the entire payment for DRG 111. The commenter noted that this is a straightforward issue, and recommended that these cases be assigned specifically to DRG 110.

Response: DRGs 110 and 111 are what we refer to as paired DRGs. Paired DRGs are exactly the same as each other with regard to the principal diagnosis and procedure codes in most cases. However, other aspects of the patient's case have a bearing on DRG assignment, such as the patient's age or the secondary diagnoses (which determine comorbidities or complications in appropriate DRGs). In this case, DRGs 110 and 111 are divided based on the presence or absence of secondary diagnosis codes. If there are no secondary diagnosis codes present, the case will be assigned to DRG 111. It has been our experience that patients not having secondary diagnoses are less expensive for the hospital to treat, thereby resulting in a lower weighted DRG assignment.

Hospitals should code their records completely, recording and submitting all relevant diagnosis and procedure codes having a bearing on the current admission. As noted previously, payment for each DRG is based on the average charges for cases assigned to that DRG as submitted to us by hospitals.

3. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Refusions

We have received questions from correspondents regarding the appropriateness of the spinal fusion DRGs: DRG 496 (Combined Anterior/Posterior Spinal Fusion); DRG 497 (Spinal Fusion with CC); and DRG 498 (Spinal Fusion without CC). Several correspondents expressed concern about the inclusion of all refusions of the spine into one procedure code, 81.09 (Refusion of spine, any level or technique). The correspondents pointed out that because all refusions using any technique or level are in this one code,

all of these cases are assigned to DRG 497 and DRG 498. They also pointed out that fusion cases involving both an anterior and posterior technique are assigned to DRG 496. Although cases with the refusion code that involve anterior and posterior techniques would appear to be more appropriately assigned to DRG 496, this is not the case.

We recognized this limitation in the refusion codes and further acknowledged that this limitation in the ICD–9–CM coding system creates DRG problems by preventing the assignment to DRG 496 even when both anterior and posterior techniques are used for refusion cases. Therefore, we referred the issue to the ICD–9–CM Coordination and Maintenance Committee and requested the Committee to consider code revisions for the refusions of the spine during its year 2000 public meetings.

After its deliberations, the Committee approved a series of new procedure codes for refusion of the spine that could lead to improvements within DRGs 497 and 498. These new codes, listed below, go into effect on October 1, 2001.

81.30 Refusion of spine, not otherwise specified
81.31 Refusion of atlas-axis spine
81.32 Refusion of other cervical spine, anterior technique
81.33 Refusion of other cervical spine, posterior technique
81.34 Refusion of dorsal and dorsolumbar spine, anterior technique
81.35 Refusion of dorsal and dorsolumbar spine, posterior technique
81.36 Refusion of lumbar and lumbosacral spine, anterior technique
81.37 Refusion of lumbar and lumbosacral spine, lateral transverse process technique
81.38 Refusion of lumbar and lumbosacral spine, posterior technique
81.39 Refusion of spine, not elsewhere classified

As previously stated, all refusions of the spine and corrections of the pseudarthrosis of the spine are assigned to code 81.09. Code 81.09, which is always assigned to DRG 497 or DRG 498, includes refusions at any level of the spine using any technique. With the creation of the new procedure codes listed above, it will be possible to determine the level of the spine at which the refusion is performed, as well as the technique used, and assign the case to a more appropriate DRG.

These new procedure codes should greatly improve our ability to determine the level and technique used in the refusion.

In the past, we have assigned new ICD–9–CM codes to the same DRG to which the predecessor code was assigned. In the proposed rule, we explained that if this practice were followed, these new codes would have been assigned to DRG 497 and 498 as they are currently. After data became available, we would have considered moving them to other DRGs. However, in accordance with section 533(a) of Public Law 106–554, which requires more expeditious methods of recognizing new medical services or technology under the inpatient hospital prospective payment system, we will reconsider this longstanding practice when possible. Since the new codes clearly allow us to identify cases where the technique was either anterior or posterior and these cases are clinically similar and, therefore, should be handled in the same fashion, we proposed to immediately assign these cases on the same basis as the fusion codes (81.00 through 81.09). We would not wait for actual claims data before making this change. These assignments are reflected in Chart 6 and also can be found in Table 6B, in section V. of the Addendum to this final rule.

Comment: One commenter supported the creation of the ICD–9–CM codes for refusions as well as their proposed DRG assignments.

Response: We appreciate the support of the commenter and are adopting the proposed DRG assignments for refusions of spine as final.

b. Fusion of Cervical Spine

In the proposed rule we discussed an inquiry concerning the spinal DRGs that focused on fusions of the cervical spine. The inquirer stated that there was a significant difference between inpatients who undergo anterior cervical spinal fusion and other types of spinal fusion in regard to treatment, recovery time, costs, and risk of complications. Anterior cervical spinal fusions are assigned to procedure code 81.02 (Other cervical fusion, anterior technique). The inquirer pointed out that anterior cervical fusions differ significantly from anterior techniques at other levels since the anatomic approach is far less invasive. Thoracic anterior techniques require working around the cardiac and respiratory systems in the chest cavity, while lumbar anterior techniques require working around bowel and digestive system and the abdominal muscles. The inquirer recommended that code 81.02 be removed from DRGs 497 and 498 and grouped separately.

We analyzed claims data from the FY 2000 MedPAR file containing hospital bills received through May 31, 2000, and confirmed that charges are lower for fusions of the cervical spine than fusions of the thoracic and lumbar spine. This was true for both anterior and posterior cervical fusions of the spine. Our medical consultants agree that the data and their clinical analysis support the creation of new DRGs for cervical fusions of the spine. We proposed to remove procedure codes 81.02 and 81.03 from the spinal fusion DRGs (currently, DRGs 497 and 498) and assign them to new DRGs for cervical spinal fusion with and without CC. We also proposed four groupings for fusion DRGs. The net effect of this change is an increase in the weights for DRGs 497 and 498, since the lower charges for the cervical fusions would be removed. The average standardized charge for all spinal fusions with CCs was $26,957. For all spinal fusions without CCs, the average charge was $16,492. The table below also shows average standardized charges for these types of cases before and after the revisions.

Revised spinal fusion DRGs	Average charge before revisions	Average charge after revisions
DRG 497 Spinal Fusion Except Cervical with CC	$26,957	$36,821
DRG 498 Spinal Fusion Except Cervical without CC	17,492	26,297
DRG 519 Cervical Spinal Fusion with CC	.....	26,957
DRG 520 Cervical Spinal Fusion without CC	.....	16,492

Based on the groupings, we proposed the creation of two new DRGs: DRG 519 (Cervical Spinal Fusion with CC); and DRG 520 (Cervical Spinal Fusion without CC). The procedure codes that would be included in the DRGs 519 and 520 are reflected in Chart 6 below.

We also proposed to add the new ICD–9–CM procedure codes for refusion of the cervical spine (81.32 and 81.33) to the new cervical spine fusion DRGs because they are clinically similar.

In addition, we proposed to retitle DRG 497 ''Spinal Fusion Except Cervical with CC'' and DRG 498 ''Spinal Fusion Except Cervical without CC.'' The retitled DRGs 497 and 498 would retain fusion codes 81.00, 81.01, and 81.04 through 81.08 and include the new refusion codes 81.30, 81.31, and 81.34 through 81.39, as reflected in Chart 6 below.

Comment: One commenter commended the creation of the new ICD–9–CM codes for spinal refusions and the development of the new DRGs for cervical fusions. This commenter, a manufacturer of devices used for spinal fusions, agreed that cervical fusions on average cost less than lumbar and thoracic fusions. Another commenter who supported the creation of the new DRGs mentioned that this classification would more appropriately reflect the resources used in the varying cases.

Two commenters asserted that DRGs 497 and 498 fail to take into account the cost variations when multi-level spinal fusions are performed. The commenters stated that the cost and complexity of a discharge varies substantially depending on the number of levels performed as part of a fusion procedure. Commenters recommended that new ICD–9–CM procedure codes be created for multi-level spine procedures to track and measure costs. The current ICD–9–CM codes do not differentiate between the number of levels that are fused. The commenter defined multi-level as three or more vertebral segments, either anterior or posterior, or both. In addition, the commenter recommended that these new multi-level fusion codes be assigned to the higher weighted DRG 496. The commenter recommended that DRG 496 be renamed ''Multi-Level Spine Procedure Anterior and/or Posterior for Stabilization and/or Correction and/or Refusion.''

Response: We agree that the current ICD–9–CM procedure codes do not differentiate between the number of levels fused. This proposal will be addressed by the ICD–9–CM Coordination and Maintenance Committee at its November 1, 2001 meeting. A potential problem with this recommendation will be the need to avoid overlapping codes. The current fusion codes are based on an axis of the level of the fusion (cervical or lumbar) and an additional axis of the approach (anterior, posterior, or lateral transverse). Devising a modified or additional scheme that utilizes an additional axis of the number of disks fused may be quite challenging. If this scheme requires the use of a set of codes from the new Chapter 17, we could quickly use up these currently empty codes. As far as the recommendation to include these new multi-level fusion codes in DRG 496, this issue will be deferred until after the coding issue is addressed. If new codes are created, they will be included in an upcoming proposed rule along with their proposed DRG assignment.

Since there was support for the proposed changes to the spinal DRGs, these will be implemented as final changes effective October 1, 2001.

c. Posterior Spinal Fusion

We received other correspondence regarding the current DRG assignment for code 81.07, Lumbar and lumbosacral fusion, lateral transverse process technique. The correspondent stated that physicians consider code 81.07 to be a posterior procedure. The patient is placed prone on the operating table and the spine is exposed through a vertical midline incision. The correspondent pointed out that code 81.07 is not classified as a posterior procedure within DRG 496 (Combined Anterior/Posterior Spinal Fusion). Therefore, when 81.07 is reported with one of the anterior techniques fusion codes, it is not assigned to DRG 496. The correspondent recommended that code 81.07 be added to the list of posterior spinal fusion codes for use in determining assignment to DRG 496.

In the proposed rule, we indicated that we consulted with our clinical advisors and they agreed that this addition should be made. Since we proposed to handle the new refusion codes in the same manner as the fusion codes, we also proposed to assign DRG 496 when 81.37 is used with one of the anterior technique fusion or refusion codes. This would be similar to the manner in which code 81.07 is classified. For assignment to DRG 496, we would consider codes 81.02, 81.04, 81.06, 81.32, 81.34, and 81.36 to be anterior techniques and codes 81.03, 81.05, 81.07, 81.08, 81.33, 81.35, and 81.38 to be posterior techniques.

CHART 6.—REVISED COMPOSITION OF DRGS 496, 497, AND 498 AND COMPOSITION OF DRG 519 AND 520 IN MDC 8

Diagnosis and procedure codes	Existing DRG 496		Retained in or Added to existing DRG 497	Retained in or Added to existing DRG 498	Included in DRG 519 included in DRG 520	
	Assigned as anterior techniques	Assigned as posterior techniques				
Principal or Secondary Procedure Codes:						
81.00 Spinal fusion, not otherwise specified	.....	.....	X	X	.....	.....
81.01 Atlas-axis fusion	.....	.....	X	X	.....	.....
81.02 Other cervical fusion, anterior technique	X	.....	.....	.....	X	X
81.03 Other cervical fusion, posterior technique	.....	X	.....	.....	X	X
81.04 Lumbar and lumbosacral fusion, anterior technique	X	.....	X	X	.....	.....
81.05 Lumbar and lumbosacral fusion, posterior technique	.....	X	X	X	.....	.....
81.06 Lumbar and lumbosacral fusion, anterior technique	X	.....	X	X	.....	.....
81.07 Lumbar and lumbosacral fusion, lateral transverse process technique	.....	X	X	X	.....	.....
81.08 Lumbar and lumbosacral fusion, posterior technique	.....	X	X	X	.....	.....

CHART 6.—REVISED COMPOSITION OF DRGS 496, 497, AND 498 AND COMPOSITION OF DRG 519 AND 520 IN MDC 8—Continued

Diagnosis and procedure codes	Existing DRG 496		Retained in or Added to existing DRG 497	Retained in or Added to existing DRG 498	Included in DRG 519 included in DRG 520	
	Assigned as anterior techniques	Assigned as posterior techniques				
81.30 Refusion of spine, not otherwise specified			X	X		
81.31 Refusion of atlas-axis spine			X	X		
81.32 Refusion of other cervical spine, anterior technique	X				X	X
81.33 Refusion of other cervical spine, posterior technique		X			X	X
81.34 Refusion of dorsal and dorsolumbar spine, anterior technique	X		X	X		
81.35 Refusion of dorsal and dorsolumbar spine, posterior technique		X	X	X		
81.36 Refusion of lumbar and lumbosacral spine, anterior technique	X		X	X		
81.37 Refusion of lumbar and lumbosacral spine, posterior technique		X	X	X		
81.38 Refusion of lumbar and lumbosacral spine, posterior technique		X	X	X		
81.39 Refusion of spine, not elsewhere classified			X	X		

There was no opposition expressed to the changes proposed for posterior spinal fusions; therefore, we are adopting the proposed changes as final.

d. Spinal Surgery

The California Division of Workers' Compensation notified us of a possible problem with the following spinal DRGs:

DRG 496 (Combined Anterior/Posterior Spinal Fusion)
DRG 497 (Spinal Fusion with CC)
DRG 498 (Spinal Fusion without CC)
DRG 499 (Back & Neck Procedures except Spinal Fusion with CC)
DRG 500 (Back & Neck Procedures except Spinal Fusion without CC)

The Division of Workers' Compensation uses the DRG categories developed by CMS to classify types of hospital care. However, instead of using CMS' weights for determining reimbursement for inpatient services, the Division sets a global fee for all inpatient medical services not otherwise exempted. This fee is established by multiplying the product of the DRG weight (or revised DRG weight for a small number of categories) and the health facility's composite factor by 1.20 to get the maximum amount for worker compensation admissions.

The Division of Workers' Compensation has received reports that the formula it uses for reimbursing cases may be providing inadequate reimbursement. California hospitals and orthopedists have reported that certain spinal surgery DRGs (DRGs 496 through 500) may involve different types of care and/or technologies than those in use at the time these groups were formulated. Health care providers in California report ''recent increased use of the new implantation devices, hardware, and instrumentation, coupled with requirements for intensive hospital services accompanying use of new procedures, has led to inadequate reimbursement in these DRGs.'' As a short-term response to these concerns, the California Division of Workers' Compensation is exempting the costs of hardware and instrumentation from the global fee of the fee schedule for DRGs 496 through 500. The Division also requested that CMS examine these DRGs for any potential problem under the Medicare reimbursement system.

The ICD–9–CM coding system does not capture specific types of implantation devices, hardware, and instrumentation. Therefore, we were not able to verify the claim that these new devices have led to increased costs in specific cases. We believe that the adoption of a more detailed coding system, such as ICD–10–PCS, would supply greater amounts of detail on these items. However, in the short term, it is not possible to identify a specific problem that involves implantation devices, hardware, and instrumentation.

Comment: As previously stated, we received support for the proposed changes to the spinal fusion DRGs. As was also stated, one commenter pointed out that the current ICD–9–CM codes do not specify the number of levels fused, nor do they specify the types of devices used.

One commenter, who manufactures spinal fusion devices, commended the new ICD–9–CM codes for refusions and the new DRGs for cervical fusions. This commenter also requested new codes specifying the number of levels fused. The commenter stated that typically two devices are used per level and therefore, with increased levels, there would be an increase in the number of infusion devices. The commenter recommended new codes for multi-level spinal fusions, but did not recommend new codes that would specify particular types of devices.

Responses: This coding issue will be addressed at future meetings of the ICD–9–CM Coordination and Maintenance Committee. If new codes are created, their DRG assignment would be addressed in a subsequent proposed rule.

4. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)

We have received correspondence from a manufacturer of an implantable vascular device requesting that code 86.07 (Insertion of totally implantable vascular access device [VAD]) be assigned as an operative procedure in MDC 11, to DRG 315 (Other Kidney & Urinary Tract O.R. Procedures). This request was inadvertently omitted from the May 4, 2001 proposed rule. Therefore, we are taking this opportunity to discuss possible designation of this procedure code as a code affecting DRG assignment in MDC 11.

Procedure code 86.07 describes the implantation of a VAD into the chest wall and blood vessels of a patient's upper body. Patients requiring this particular device have been diagnosed with renal (kidney) failure. Insertion of a VAD allows access to the patient's blood for dialysis purposes when other sites for hemodialysis have been exhausted. According to representatives from the manufacturer of one particular VAD used for hemodialysis, this device costs the hospitals $1,750, and is usually inserted in the outpatient setting as opposed to admission for insertion of the device.

The GROUPER program does not recognize code 86.07 as a procedure in other than MDC 9 (Disease and Disorders of the Skin, Subcutaneous Tissue and Breast), in DRGs 269 and 270 (Other Skin, Subcutaneous Tissue & Breast Procedure, with and without CC). Therefore, its presence in any other MDC does not affect DRG assignment. Patients who are admitted with renal failure and who have a VAD inserted will be assigned to DRG 316 (Renal Failure), absent any other surgical procedures. DRG 316 is a medical DRG with a lower relative weight than cases in the surgical DRGs within the same MDC.

We extensively reviewed the MedPAR data. We found that code 86.07 appeared in 358 different DRGs. Of these 358 DRGs, 173 include additional procedures recognized by GROUPER and are therefore considered surgical, while 185 are medical. Because of the space limitations of the ICD–9–CM, code 86.07 is used to describe VAD devices used for other purposes than hemodialysis.

We looked specifically at the cases within DRGs 315 and 316 as shown in the two tables below:

DRG 315 (SURGICAL)

	With code 86.07	Without code 86.07
Number of Cases	421	19,815.
Average Length of Stay	12.5 days	6.8 days.
Average Charges	$39,946	$23,061.

DRG 316 (MEDICAL)

	With code 86.07	Without code 86.07
Number of Cases	1,020	19,815.
Average Length of Stay	10.2 days	6.6 days.
Average Charges	$27,730	$15,045.

Cases containing code 86.07 have higher average lengths of stay as well as higher average charges than cases not containing this code. We further examined the total number of reported procedures, as well as the range of average charges across both DRGs, for cases containing code 86.07. Both DRGs contain a significant number of additional procedures. The nature of these procedures varies widely, including such divergent procedures as X-rays and scans, injections, dental extraction, cardiac catheterization, aneurysm repair, and laparoscopic cholecystectomy. We also identified 24 cases in DRG 315 and 28 cases in DRG 316 with multiple insertions of the VAD. We believe those instances where the VAD is inserted as an inpatient procedure involve cases where other complications exist, leading to the higher average charges noted above. We are not assigning code 86.07 to DRG 315 as a surgical procedure, but will continue to consider possible alternative specifications of these DRGs.

Additionally, we take this opportunity to clarify correct coding practice. It has come to our attention that a brochure is being distributed with the product that advocates coding insertion of the Lifesite® Hemodialysis Access System using ICD–9–CM procedure code 86.07 in addition to code 39.93 (Insertion of vessel-to-vessel cannula). Inclusion of code 39.93 will force these cases into DRG 315, the higher weighted surgical DRG. Our data review showed 33 such cases of double coding. We would caution hospitals that the use of code 39.93, in the absence of the actual procedure, is erroneous. According to our vascular surgeon consultant, the LifeSite® Hemodialysis Access System as presented to us is not a vessel-to-vessel cannula. It is a device inserted into a vessel. Therefore, providers submitting code 39.93 without the actual procedure having been performed are at risk for review of fraudulent coding practice and DRG upcoding.

This same product brochure contains the name and telephone number of a nationally recognized coding specialist. The addition of this specialist's name and number was included without her knowledge or consent. We take this opportunity to reiterate that LifeSite® Hemodialysis Access System is correctly coded using 86.07 alone.

5. MDC 12 (Diseases and Disorders of the Male Reproductive System)

At its May 11, 2000 public meeting, the ICD–9–CM Coordination and Maintenance Committee considered a request from a manufacturer to create a unique code for the procedure Penile plethysmography with nerve stimulation in DRG 334 (Major Male Pelvic Procedures with CC). The penile plethysmography is a test that can be performed during a radical prostatectomy procedure. During the course of the procedure, the physician places a probe within an area where the prostatic nerves are thought to be located and is able to detect minor changes in penile tumescence or detumescence. This reaction tells the physician that the nerve bundles have been located, which may aid the physician in performing a nerve-sparing radical prostatectomy procedure with precision. The nerve bundles can also be restimulated at the conclusion of the procedure, providing immediate feedback as to whether erectile function will be restored after surgery.

After a presentation on the nerve identifying procedure and review of existing ICD–9–CM codes, the ICD–9–CM Coordination and Maintenance Committee determined that the existing

code 89.58 (Plethysmogram) adequately describes this test.

Radical prostatectomies for patients with cancer of the prostate are grouped in either DRG 334 (Major Male Pelvic Procedures with CC) or DRG 335 (Major Male Pelvic Procedures without CC). We have received a request from a manufacturer of a nerve-identifying device to assign cases containing code 89.58 into DRG 334 only, not into DRG 335. DRG 334 results in higher payments to hospitals. For FY 2002, DRG 334 has a relative weight of 1.5177, and DRG 335 has a relative weight of 1.1047. The manufacturer requested that we designate code 89.58 as an operating room procedure code that would be recognized by the GROUPER software, and make that code applicable only to DRG 334. The manufacturer believed that this would serve to take any cases of nerve sparing out of the lower paying DRG 335, and would make the technology more attractive to hospitals. As paired DRGs 334 and 335 are currently structured, they differ only in whether or not a secondary diagnosis identified as a CC is recorded.

We examined those cases in DRG 334 to which the procedure code for prostatectomy was assigned. Of the total 7,241 cases in DRG 334 identified, 5,611 of these cases contained procedure code 60.5 (Radical prostatectomy). Only three of the prostatectomy cases included code 89.58. There are not a sufficient number of cases on which to base an assessment of the payment for this procedure. Therefore, we did not propose to modify the assignment of code 89.58.

We received one comment on this proposal.

Comment: The commenter argued that the analysis conducted on the procedure code assignment of 89.58 was incomplete, as it did not include evaluation of DRG 335 in the calculations. The commenter added that DRG also includes radical prostatectomies for patients with cancer of the prostate.

Response: We apologize for the omission. Our review of data on DRG 335 showed that the DRG contained 8,125 total cases. There were 8,117 cases that did not contain procedure code 89.58; these cases had average total charges of $12,808. There were 8 cases in this group containing code 89.58. These 8 cases had average total charges of $16,366. We found a subset of 7,050 cases containing procedure code 60.5; these cases had average total charges of $12,772. Within this subset, only 7 cases were reported containing codes 60.5 and 89.58. These 7 cases had average total charges of $16,593.

Even including these additional cases, we identified very few cases in our analysis. Therefore, we are adopting as final our original proposed decision not to modify the assignment of code 89.58 by assigning it exclusively to DRG 334 within MDC 12. However, we will continue to monitor this procedure to determine whether a change in DRG assignment is warranted in the future.

6. MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period)

DRG 390 (Neonate with Other Significant Problems) contains newborn or neonate cases with other significant problems not assigned to DRGs 385 through 389, DRG 391, or DRG 469. To be assigned to DRG 389 (Full Term Neonate with Major Problems), the neonate must have one of the principal or secondary diagnosis listed under this DRG. A neonate is assigned to DRG 390 when the neonate has a principal or secondary diagnosis of newborn or neonate with other significant problems that are not assigned to DRG 385 through 389, 391, or 469.

We have received correspondence suggesting a number of changes to be made to DRGs 398 and 391. These changes involve removing two codes from DRG 389 and adding 17 codes to DRG 391, as described below.

a. DRG 389 (Full Term Neonate with Major Problems)

The correspondent suggested removing the following codes from DRG 389 and assigning them to DRG 390:

773.0 Hemolytic disease due to RH isoimmunization

773.1 Hemolytic disease due to ABO isoimmunization

The correspondent stated that hemolytic disease due to RH isoimmunization or due to ABO isoimmunization should not be considered a major problem. The correspondent recommended that these two conditions be classified as significant problems instead and thus assigned to DRG 390.

Our medical consultants sought additional advice from the National Association of Children's Hospitals and Related Institutions (NACHRI). (CMS contracts with the 3M Health Information Systems to maintain the DRG system. The medical experts at 3M evaluate proposed DRG changes from a clinical perspective. These medical consultants assist CMS in evaluating alternative proposals.) NACHRI and our medical consultants agree that it is appropriate to remove codes 773.0 and 773.1 from DRG 389. Therefore, we proposed to remove 773.0 and 773.1 from DRG 389 so that neonates with these conditions are assigned to DRG 390.

Comment: Several commenters supported the proposed revisions for newborns within MDC 15. One commenter stated that the code assignments mentioned in the proposed rule are more appropriately classified based on their clinical attributes. Another commenter agreed with the proposed changes, but requested that an additional code be added to those being moved to DRG 391 (Normal Newborn). Specifically, the commenter requested that code 779.3, Feeding problems in newborns, be listed under DRG 391. Currently, when this code is listed as a secondary code, it results in the assignment of the neonate to DRG 390. The commenter stated that this condition and its resource consumption should not cause the neonate to be classified under DRG 390.

Response: We discussed this additional issue with our medical consultants and they agreed that code 779.3 should also be listed under DRG 391. They concurred that the addition of this code as a secondary diagnosis should not lead to the newborn being classified as having a significant problem. Therefore, code 779.3 will be included among the codes being moved to DRG 391 as of October 1, 2001.

Comment: One commenter suggested that codes 773.0 and 773.1 be removed from DRG 387 (Prematurity with major problems) in addition to DRG 389. The list of major problems in DRGs 389 and 387 mirror each other. The only difference is that DRG 387 includes premature newborns. The commenter asked us to consider codes 773.0 and 773.1 as significant problems for newborns and classify them into DRG 390, which would make them applicable for premature and full-term newborns.

Response: We agree with the commenter. We are removing codes 773.0 and 773.1 from DRG 389 as well as DRG 387. This removal will result in these cases being assigned to DRG 390 (Neonate with Other Significant Problems).

b. DRG 391 (Normal Newborn)

We also have received correspondence with recommendations for changes to DRG 391. The correspondent pointed out that the following secondary codes currently lead to the assignment of the neonate to DRG 390 (Neonate with Other Significant Problems). The correspondent believed that the conditions described by these codes

should not cause the neonate to be classified under DRG 390 when reported as a secondary diagnosis. The correspondent recommended that these conditions be listed under DRG 391 (Normal Newborn).

478.1 Other diseases of nasal cavity and sinuses
520.6 Disturbances in tooth eruption
623.8 Other specified noninflammatory disorders of vagina
709.00 Dyschromia, unspecified
709.01 Vitiglio
709.09 Dyschromia, Other
744.1 Accessory auricle
754.61 Congenital pes planus
757.33 Congenital pigmentary anomalies of skin
757.39 Other specified anomaly of skin
764.08 ''Light for dates'' without mention of fetal malnutrition, 2,000–2,499 grams
764.98 Fetal growth retardation, unspecified, 2,000–2,499 grams
772.6 Cutaneous hemorrhage
794.15 Abnormal and auditory function studies
796.4 Other abnormal clinical findings
V20.2 Routine infant or child health check
V72.1 Examination of ears and hearing

Our medical consultants also sought the advice of NACHRI on this recommendation. NACHRI reviewed the list of codes and agreed that none of these conditions should be considered to be a significant problem for a neonate. NACHRI concurred that neonates with these secondary diagnoses should be classified as normal newborns. Therefore, we proposed to add the codes listed above to DRG 391 and not classify them to DRG 390 when reported as a secondary diagnosis.

Comment: One commenter expressed concern that the weights assigned to five newborn DRGs (DRGs 385, 368, 387, 388, and 389) are undervalued. The commenter pointed out that legislation mandating Early Hearing Detection and Intervention (EHDI) has been passed in 35 States plus the District of Columbia. In these States, hearing screening must be performed prior to the newborn's discharge from the hospital unless prevented by medical complications. The cost per screening ranges from $15 to $30, which includes personnel, supplies, and equipment costs which are amortized over 3 years. The screening also includes costs for babies that require diagnostic evaluation.

The commenter requested that data from States that have not implemented EHDI programs be deleted from the Medicare supplemental database for, at a minimum, DRG 391 (Normal Newborn). The commenter stated that non-Medicare data used for developing the weights for the five newborn DRGs do not represent average costs if some of the 19 States that supply supplemental non-Medicare data are States that perform hearing screenings on less than 90 percent of newborns. The commenter further requested that we use data only from States that have EHDI programs that are operational at the 90 percent level. The commenter provided a list of States that meet these criteria.

Response: While we appreciate the commenter's furnishing us with information on the costs of providing services such as hearing screenings, it would be inappropriate for us to use this one service to determine whether or not to include a State's data because the State does not provide the service at a 90-percent level. The DRG weights are based on averages. As hospitals elect to include or exclude services, the weights will change over time. Therefore, we are not developing a criterion to exclude hospital data from States that do not have a 90-percent compliance level with EHDI.

Comment: One commenter noted that new procedure code 75.38, Fetal pulse osimetry, was classified as a nonoperative procedure code in Table 6B of the Addendum of the proposed rule. As a nonoperative procedure, it was not assigned to an MDC or to specific DRGs. The commenter requested that we assign code 75.38 to MDC 14 (Pregnancy, Childbirth and Puerperium), and the following DRGs:

DRG 370—(Caesarean Section with CC)
DRG 371—(Caesarean Section without CC)
DRG 372—(Vaginal Delivery with Complicating Diagnosis)
DRG 373—(Vaginal Delivery without CC)

The commenter believed it was critical that the clinical benefits and use of fetal pulse oximetry be closely tracked in order to monitor clinical outcomes and to recognize potential economic advantages. The commenter acknowledged that most labor and delivery patients are not Medicare beneficiaries. However, other third party payers benchmark hospital inpatient payment rates from Medicare DRGs. The commenter stated that if code 75.38 does not contribute or link to a DRG, it is often simply not coded. The commenter further stated that fetal oximetry is an exciting and significant emerging technology and that much knowledge can be gained by understanding its usage in the context of labor and delivery services.

Response: The commenter requested that 75.38 be assigned to the DRGs for deliveries (DRG 370 through 373). However, these DRGs are currently assigned based on the procedure codes for the specific type of delivery (caesarian or vaginal). Adding the procedure code 75.38 to these delivery DRGs would not affect the DRG assignment. The cases would still be assigned to the appropriate DRG based on the type of delivery, not whether the baby received fetal pulse oximetry. If the commenter is suggesting that the fetal pulse oximetry code, on its own, should lead to the DRG assignment, this option is not workable. Without knowing that the mother actually delivered, and the type of delivery, one would not be able to assign the case to one of the delivery DRGs. Once one knew through the procedure codes that the mother delivered, and the type of delivery, the addition of 75.38 would not add to the DRG assignment.

The commenter did not make an argument as to why 75.38 was incorrectly classified as a nonoperating room procedure. While we appreciate the commenter's desire that this new procedure code be used, assigning the code to existing DRGs is not consistent with the structure of DRGs. Procedure codes are only assigned to DRGs when they effect the DRG assignment logic. Therefore, we are not changing the operating room status of code 75.38, nor are we adding it to the delivery DRGs. Code 75.38 will be considered a nonoperative procedure.

c. Medicare Code Editor Changes

The Medicare Code Editor (MCE) is a front-end software program that detects and reports errors in the coding of claims data. The age conflict edit detects inconsistencies between a patient's age and any diagnosis on the patient's record. A subset of diagnoses is considered valid only for patients over the age of 14 years. These diagnoses are identified as ''adult'' diagnoses and range in age from 15 through 124 years. Therefore, any codes included on the Newborn Diagnoses edit are valid only for patients under age 14.

It has come to our attention that cases including the ICD–9–CM code 770.7, Chronic respiratory disease arising in the perinatal period, are being rejected. However, a condition such as bronchopulmonary dysplasia always originates in the perinatal period, so regardless of the patient's age, this condition is always coded as 770.7. The age at which the diagnosis was established or the age at continuing treatment does not affect the assignment of code 770.7.

Because correct coding is causing these claims to be rejected, in the May 4 proposed rule we proposed to remove code 770.7 from the Newborn Diagnoses edit in the MCE, as well as remove it from DRG 387 (Prematurity with Major Problems) and DRG 389 (Full Term Neonate with Major Problems). Clinical conditions in code 770.7, such as pulmonary fibrosis, would group to DRG 92 (Interstitial Lung Disease with CC) and DRG 93 (Interstitial Lung Disease without CC). Therefore, we proposed the addition of code 770.7 to DRGs 92 and 93, as they are most similar clinically. We indicated that we would monitor these cases in upcoming MedPAR data to ascertain that the cases consume similar resources.

We received no comments on these proposals, and are, therefore, adopting the change as final.

7. MDC 20 (Alcohol/Drug Use and Alcohol/Drug-Induced Organic Mental Disorders)

DRG 434 (Alcohol/Drug Abuse or Dependency, Detoxification or Other Symptomatic Treatment with CC) is assigned when the patient has a principal diagnosis of alcohol or drug abuse or dependence along with a secondary diagnosis classified as a CC. If these patients do not have a CC, they are assigned to DRG 435 (Alcohol/Drug Abuse or Dependency, detoxification or Other Symptomatic Treatment without CC). When the patients receive rehabilitation and detoxification therapy during the stay, they are assigned to DRG 437 (Alcohol/Drug Dependence, Combined Rehabilitation and Detoxification Therapy). If the patients receive only rehabilitation therapy, they are assigned to DRG 436 (Alcohol/Drug Dependence with Rehabilitation Therapy).

We have received inquiries as to why the relative weight for DRG 437, which includes both rehabilitation and detoxification (for FY 2001, the relative weight is .6606, with a geometric mean length of stay of 7.5) is lower than the FY 2001 relative weight for DRG 434, which includes only detoxification (.7256, with a geometric mean length of stay of 3.9). Likewise, the FY 2001 relative weight for DRG 436, which includes only rehabilitation (.7433), is higher than the FY 2001 relative weight for DRG 437, which includes combined rehabilitation and detoxification therapy (.6606). The inquirers indicated that those patients receiving the combination therapy would be expected to have a longer length of stay, require more services, and, therefore, be more costly to treat.

We analyzed data from the FY 2000 MedPAR file and did not find support for the inquirers' assertion that combination therapy is more costly to treat. The relative weights indicate that the presence of a CC in DRG 434 leads to a significantly higher weight than is found in DRG 435, which does not have a CC. Therefore, we analyzed the alcohol/drug DRGs and focused on eliminating the distinction between rehabilitation and rehabilitation with detoxification and assessing the impact of CCs. We combined data on DRGs 436 and 437 and then subdivided the data based on the presence or absence of a CC. The following table contains the results of the analysis.

AVERAGE CHARGES FOR CASES—WITH AND WITHOUT CCS

DRGS	With CC			Without CC		
	Count	Charge	Length of stay	Count	Charge	Length of stay
Detoxification Cases—DRG 434 and DRG 435	3,298	$8,548	5.0	9,689	$5,111	4.1
All Rehabilitation Cases—DRG 436 and DRG 437	3,298	8,117	10.1	4,473	7,407	9.6

We found that, for both the detoxification and rehabilitation DRGs, the with-CC group has higher charges than the without-CC group. However, the with-CC groups still contain the anomaly that the detoxification DRG 434 has a slightly higher average charge than the combined rehabilitation DRGs 436 and 437. It appears that any significant medical problems as indicated by the presence of a CC dominate the cost incurred by hospitals for treating alcohol and drug abuse patients. For the without-CC groups, the detoxification DRG 435 has substantially lower average charges than the combined rehabilitation DRGs 436 and 437. Because the average charges of the with-CC for both the detoxification DRG 434 and combined rehabilitation DRGs 436 and 437 have similar average charges, we proposed to combine these two groups.

Based on the results of our analysis, we proposed to restructure MDC 20 as follows. We first identified those cases with a principal diagnosis within MDC 20 where the patient left against medical advice. These cases are found in DRG 433 (Alcohol/Drug Abuse or Dependence, Left Against Medical Advice (AMA)). We next identified all remaining cases with a principal diagnosis within MDC 20 where there was a CC. We assigned these cases to a new DRG, (Alcohol/Drug Abuse or Dependence with CC). The remaining cases (without CC and did not leave against medical advice) were then divided into two new DRGs based on whether or not the patient received rehabilitation (Alcohol/Drug Abuse or Dependence without CC, with Rehabilitation Therapy; and Alcohol/Drug Abuse or Dependence without CC, without Rehabilitation Therapy).

The following table illustrates the number of patients and average charges for each of the four proposed DRGs.

FREQUENCIES AND AVERAGE CHARGES FOR NEW DRGS

DRG	Group title	Number of cases	Average charges
433	Alcohol/Drug Abuse or Dependence, Left Against Medical Advice	3,509	$3,855
521	Alcohol/Drug Abuse or Dependence with CC	18,235	8,470
522	Alcohol/Drug Abuse or Dependence without CC, with Rehabilitation Therapy	4,473	7,407
523	Alcohol/Drug Abuse or Dependence without CC, without Rehabilitation Therapy	9,689	5,111

This table illustrates that groups based first on the presence of CC and then on whether or not the patient receives rehabilitation therapy provide a much better explanation of differences in charges. Therefore, we proposed to retain DRG 433, make DRGs 434 through 437 invalid, and create new DRGs 521, 522, and 523 to include the diagnosis and procedure codes reflected in Chart 7 below.

CHART 7.—RESTRUCTURE OF MDC 20 (ALCOHOL/DRUG USE AND ALCOHOL/DRUG-INDUCED ORGANIC MENTAL DISORDERS)

Diagnosis and procedure code	Included in Existing DRG 433	Included in DRG 521	Included in DRG 522	Included in DRG 523
Principal diagnosis:				
All principal diagnosis within existing MDC 20 involving cases in which patients left against medical advice (AMA)	X			
All principal diagnoses within existing MDC 20 where there is a CC and where patient did not leave against medical advice (AMA)		X		
All principal diagnoses within existing MDC 20 without CC and where patient did not leave against medical advice (AMA).				
All principal diagnoses in existing MDC 20 without CC involving cases where patients did not leave against medical advice (AMA)				X
Procedure Codes:				
94.61 Alcohol rehabilitation			X	
94.63 Alcohol rehabilitation and detoxification			X	
94.64 Drug rehabilitation			X	
94.66 Drug rehabilitation and detoxification			X	
94.67 Combined alcohol and drug rehabilitation			X	
94.69 Combined alcohol and drug rehabilitation and detoxification			X	

Comment: One commenter was uncertain as to the intent of the reclassification of the DRGs to identify alcohol/drug use and alcohol/drug-induced organic mental disorders. The commenter expressed concern that the cases associated with alcohol/drug use would have a lower overall weight relative to the overall average weight of these cases in FY 2001. The commenter requested further information on the impact of this change in the final rule. Additionally, the commenter recommended that the title for DRG 521 be changed from ''Alcohol/Drug Abuse or Dependence with CC'' to ''Alcohol/Drug Abuse with CC, with or without Rehabilitation Therapy.''

Response: As described above, for FY 2001, cases receiving combined rehabilitation and detoxification (DRG 437) had a lower relative weight than patients receiving only detoxification (DRG 434) or rehabilitation (DRG 436). Since these relative weights are derived from actual claims data, we decided to review the issue to determine if other factors had any impact. It would be expected that those patients receiving the combination therapy would have a longer length of stay, require more services, and therefore be more costly to treat. This was not supported by the data.

The factor that seems to contribute the greatest to the costs of these cases is the presence of a CC. The presence of a CC had a greater impact on the average charges than did factors such as detoxification or rehabilitation. Once the importance of this factor was determined, the cases not leaving against medical advice (DRG 433) were split on whether or not a CC was present. Those with a CC were assigned to new DRG 521. The remaining cases were then split based on whether or not rehabilitation was provided.

As can be seen from the FY 2002 relative weights in the chart below, MDC 20 patients who have a CC are considerably more expensive to treat. They have the highest relative weight among this set of DRGs. The second highest weight is assigned to MDC 20 cases without CC who also received rehabilitation services.

DRG title	Number of of cases	Final weights
DRG 433 Alcohol/Drug Abuse or Dependence, Left AMA	5,522	.2888
DRG 521 Alcohol/Drug Abuse or Dependence with CC	28,014	.7355
DRG 522 Alcohol/Drug Abuse or Dependence without CC, with Rehabilitation Therapy	6,852	.6249
DRG 523 Alcohol/Drug Abuse or Dependence without CC, without Rehabilitation Therapy	14,954	.3997

As can be seen from this chart, the majority of patients are assigned to DRG 521, which has the highest relative weight among the MDC 20 DRGs. As is the case for all DRGs, the relative weights reflect hospitals' actual charges submitted for bills in the FY 2000 MedPAR file. Data support the new splits based first on the presence of a CC and then on the presence of rehabilitation therapy. Therefore, we are adopting the proposed DRG classification changes as final without change.

While we appreciate the comment on modifying the title for DRG 521, we believe that it does not add to the clarity of the DRG. All MDC 20 patients who have not left AMA but who have a CC are assigned to DRG 521. The presence or absence of a code for rehabilitation therapy does not effect the DRG assignment for these cases. Therefore, we are adopting the proposed title as final without change.

8. MDC 25 (Human Immunodeficiency Virus Infections)

Effective October 1, 2000, ICD–9–CM diagnosis codes 783.2 (Abnormal loss of weight) and 783.4 (Lack of expected normal physiological development) were made invalid (65 FR 47171). These

two old diagnosis codes were expanded to five digits and the following new diagnosis codes were created:

783.21 Loss of weight
783.22 Underweight
783.40 Unspecified lack of normal physiological development
783.41 Failure to thrive
783.42 Delayed milestones
783.43 Short stature

These six revised codes were created in response to an industry request. Specifically, code 783.2 did not differentiate between whether the patient had lost weight recently or whether the patient was underweight. Code 783.4 was expanded to capture concepts such as failure to thrive, delayed milestones, and short stature. None of these concepts were captured in the old codes.

We listed these new codes in the August 1, 2000 final rule on the hospital inpatient prospective payment system in Table 6A—New Diagnosis Codes (65 FR 47169). At the time the final rule was published, all of these codes were assigned to DRGs 296 through 298. After the final rule was published, we received an inquiry as to why these new diagnosis codes were not included in MDC 25 as human immunodeficiency virus (HIV)-related conditions. The inquirer pointed out that the predecessor codes (783.2 and 783.4) were included in MDC 25 as HIV-related conditions and suggested that the new codes be added to MDC 25. These cases will be assigned to other MDCs if the patient does not have HIV.

In the proposed rule, we stated that we agreed that the expanded codes should have been placed in the MDC 25 as HIV-related conditions. The omission was an oversight. Therefore, we proposed to add diagnosis codes 783.21, 783.22, 783.40, 783.41, 783.42, and 783.43 as HIV-related conditions within MDC 25. When these six revised codes are reported with code 042 HIV, the patient will be classified within MDC 25.

Comment: One commenter supported the placement of codes 783.21, 783.22, 783.40, 783.41, 783.42, and 783.43, as HIV-related conditions within MDC 25.

Response: We appreciate the commenter's support and are adopting the proposed changes as final.

9. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule by which these cases are assigned to a single DRG. The surgical hierarchy, an ordering of surgical classes from most resource intensive to least, performs that function. Its application ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of DRG reclassification and recalibration, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications, to determine if the ordering of classes coincided with the intensity of resource utilization, as measured by the same billing data used to compute the DRG relative weights.

A surgical class can be composed of one or more DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single DRG (DRG 302) and the class ''kidney, ureter and major bladder procedures'' consists of three DRGs (DRGs 303, 304, and 305). Consequently, in many cases, the surgical hierarchy has an impact on more than one DRG. The methodology for determining the most resource-intensive surgical class involves weighting each DRG for frequency to determine the average resources for each surgical class. For example, assume surgical class A includes DRGs 1 and 2 and surgical class B includes DRGs 3, 4, and 5. Assume also that the average charge of DRG 1 is higher than that of DRG 3, but the average charges of DRGs 4 and 5 are higher than the average charge of DRG 2. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weight the average charge of each DRG by frequency (that is, by the number of cases in the DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other OR procedures'' as discussed below.

This methodology may occasionally result in a case involving multiple procedures being assigned to the lower-weighted DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER searches for the procedure in the most resource-intensive surgical class, this result is unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average relative weight is ordered above a surgical class with a higher average relative weight. For example, the ''other OR procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the relative weight for the DRG or DRGs in that surgical class may be higher than that for other surgical classes in the MDC. The ''other OR procedures'' class is a group of procedures that are least likely to be related to the diagnoses in the MDC but are occasionally performed on patients with these diagnoses. Therefore, these procedures should only be considered if no other procedure more closely related to the diagnoses in the MDC has been performed.

A second example occurs when the difference between the average weights for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy since, by virtue of the hierarchy change, the relative weights are likely to shift such that the higher-ordered surgical class has a lower average weight than the class ordered below it.

Based on the preliminary recalibration of the DRGs, we proposed the modification of the surgical hierarchy as set forth below. As we stated in the September 1, 1989 final rule (54 FR 36457), we are unable to test the effects of proposed revisions to the surgical hierarchy and to reflect these changes in the proposed relative weights due to the unavailability of the revised GROUPER software at the time the proposed rule is prepared. Rather, we simulate most major classification changes to approximate the placement of cases under the proposed reclassification and then determine the average charge for each DRG. These average charges then serve as our best estimate of relative resource use for each surgical class. We test the proposed surgical hierarchy changes after the revised GROUPER is received and reflect the final changes in the DRG relative weights in the final rule. Further, as discussed in section II.C. of this preamble, we anticipate that the final recalibrated weights will be somewhat different from those proposed, because they will be based on more complete data. Consequently, in the proposed rule we stated that further revision of the hierarchy, using the above principles, might be necessary in the final rule.

In the May 4 proposed rule, we proposed to revise the surgical hierarchy for the pre-MDC DRGs, MDC 5 (Diseases and Disorders of the Circulatory System), MDC 8 (Diseases

and Disorders of the Musculoskeletal System & Connective Tissue) and MDC 20 (Alcohol/Drug Use & Alcohol/Drug Induced-Organic Mental Disorders) as follows:

- In the pre-MDC DRGs, we proposed to reorder Lung Transplant (DRG 495) above Bone Marrow Transplant (DRG 481). We also proposed to reorder Simultaneous Pancreas/Kidney Transplant (DRG 512) and Pancreas Transplant (DRG 513) above Lung Transplant (DRG 495).
- In MDC 5, we proposed to reorder Cardiac Defibrillator Implants (DRGs 514 and 515) above Other Cardiothoracic Procedures (DRG 108). We also proposed to reorder Percutaneous Cardiovascular Procedures (DRGs 516, 517, and 518) above Other Vascular Procedures (DRGs 478 and 479).
- In MDC 8, we proposed to reorder Cervical Spinal Fusion (DRGs 519 and 520) above Back & Neck Procedures Except Spinal Fusion (DRGs 499 and 500).
- In MDC 20, we proposed to order as follows: Alcohol/Drug Abuse or Dependence, Left AMA (DRG 433) above Alcohol/Drug Abuse or Dependence With CC (DRG 521); Alcohol/Drug Abuse or Dependence With CC (DRG 521) above Alcohol/Drug Abuse or Dependence With Rehabilitation Therapy Without CC (DRG 522); and Alcohol/Drug Abuse or Dependence With Rehabilitation Therapy Without CC (DRG 522) above Alcohol/Drug Abuse or Dependence Without Rehabilitation Therapy Without CC (DRG 523).

Comment: One commenter expressed support for hierarchy proposals.

Response: We appreciate the commenter's support. Based on a test of the proposed revisions using the March 2001 update of the FY 2000 MedPAR file and the revised GROUPER software, we have found that the revisions are still supported by the data, and no additional changes are indicated. Therefore, we are adopting these proposed changes as final.

10. Refinement of Complications and Comorbidities (CC) List

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered a valid CC in combination with a particular principal diagnosis. Thus, we created the CC Exclusions List. We made these changes for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative coding or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. We developed this standard list of diagnoses using physician panels to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the standard list of CCs, either by adding new CCs or deleting CCs already on the list. We stated in the proposed rule that we did not propose to delete any of the diagnosis codes on the CC list at that time.

In the May 19, 1987 proposed notice (52 FR 18877) concerning changes to the DRG classification system, we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another (as subsequently corrected in the September 1, 1987 final notice (52 FR 33154)).
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for a condition should not be considered CCs for one another.
- Conditions that may not coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- The same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. The FY 1988 revisions were intended only as a first step toward refinement of the CC list in that the criteria used for eliminating certain diagnoses from consideration as CCs were intended to identify only the most obvious diagnoses that should not be considered complications or comorbidities of another diagnosis. For that reason, and in light of comments and questions on the CC list, we have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. (See the September 30, 1988 final rule (53 FR 38485) for the revision made for the discharges occurring in FY 1989; the September 1, 1989 final rule (54 FR 36552) for the FY 1990 revision; the September 4, 1990 final rule (55 FR 36126) for the FY 1991 revision; the August 30, 1991 final rule (56 FR 43209) for the FY 1992 revision; the September 1, 1992 final rule (57 FR 39753) for the FY 1993 revision; the September 1, 1993 final rule (58 FR 46278) for the FY 1994 revisions; the September 1, 1994 final rule (59 FR 45334) for the FY 1995 revisions; the September 1, 1995 final rule (60 FR 45782) for the FY 1996 revisions; the August 30, 1996 final rule (61 FR 46171) for the FY 1997 revisions; the August 29, 1997 final rule (62 FR 45966) for the FY 1998 revisions; the July 31, 1998 final rule (63 FR 40954) for the FY 1999 revisions, and the August 1, 2000 final rule (65 FR 47064) for the FY 2001 revisions.) In the July 30, 1999 final rule (64 FR 41490) we did not modify the CC Exclusions List for FY 2000 because we did not make any changes to the ICD–9–CM codes for FY 2000.

In this final rule, we are making a limited revision of the CC Exclusions List to take into account the changes that will be made in the ICD–9–CM diagnosis coding system effective October 1, 2001. (See section II.B.11. below, for a discussion of ICD–9–CM changes.) These changes are being made in accordance with the principles established when we created the CC Exclusions List in 1987.

Tables 6F and 6G in section V. of the Addendum to this final rule contain the revisions to the CC Exclusions List that will be effective for discharges occurring on or after October 1, 2001. Each table shows the principal diagnoses with changes to the excluded CCs. Each of these principal diagnoses is shown with an asterisk, and the additions or deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis.

CCs that are added to the list are in Table 6G—Additions to the CC Exclusions List. Beginning with discharges on or after October 1, 2001, the indented diagnoses will not be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

CCs that are deleted from the list are in Table 6H—Deletions from the CC Exclusions List. Beginning with discharges on or after October 1, 2001, the indented diagnoses will be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

Copies of the original CC Exclusions List applicable to FY 1988 can be obtained from the National Technical Information Service (NTIS) of the Department of Commerce. It is available in hard copy for $133.00 plus shipping and handling. A request for the FY 1988 CC Exclusions List (which should

include the identification accession number (PB) 88–133970) should be made to the following address: National Technical Information Service, United States Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161; or by calling (800) 553–6847.

Users should be aware of the fact that all revisions to the CC Exclusions List (FYs 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, and 1999) and those in Tables 6F and 6G of this document must be incorporated into the list purchased from NTIS in order to obtain the CC Exclusions List applicable for discharges occurring on or after October 1, 2001. (Note: There was no CC Exclusions List in FY 2000 because we did not make changes to the ICD–9–CM codes for FY 2000.)

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current DRG Definitions Manual, Version 18.0, is available for $225.00, which includes $15.00 for shipping and handling. Version 19.0 of this manual, which includes the final FY 2002 DRG changes, will be available in October 2001 for $225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949–0303. Please specify the revision or revisions requested.

11. Review of Procedure Codes in DRGs 468, 476, and 477

Each year, we review cases assigned to DRG 468 (Extensive OR Procedure Unrelated to Principal Diagnosis), DRG 476 (Prostatic OR Procedure Unrelated to Principal Diagnosis), and DRG 477 (Nonextensive OR Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these DRGs.

DRGs 468, 476, and 477 are reserved for those cases in which none of the OR procedures performed are related to the principal diagnosis. These DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. DRG 476 is assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

60.0 Incision of prostate
60.12 Open biopsy of prostate
60.15 Biopsy of periprostatic tissue
60.18 Other diagnostic procedures on prostate and periprostatic tissue
60.21 Transurethral prostatectomy
60.29 Other transurethral prostatectomy
60.61 Local excision of lesion of prostate
60.69 Prostatectomy NEC
60.81 Incision of periprostatic tissue
60.82 Excision of periprostatic tissue
60.93 Repair of prostate
60.94 Control of (postoperative) hemorrhage of prostate
60.95 Transurethral balloon dilation of the prostatic urethra
60.99 Other operations on prostate

All remaining OR procedures are assigned to DRGs 468 and 477, with DRG 477 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis. The original list of the ICD–9–CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the September 30, 1988 final rule (53 FR 38591). As part of the final rules published on September 4, 1990 (55 FR 36135), August 30, 1991 (56 FR 43212), September 1, 1992 (57 FR 23625), September 1, 1993 (58 FR 46279), September 1, 1994 (59 FR 45336), September 1, 1995 (60 FR 45783), August 30, 1996 (61 FR 46173), and August 29, 1997 (62 FR 45981), we moved several other procedures from DRG 468 to 477, and some procedures from DRG 477 to 468. No procedures were moved in FY 1999, as noted in the July 31, 1998 final rule (63 FR 40962); in FY 2000, as noted in the July 30, 1999 final rule (64 FR 41496); or in FY 2001, as noted in the August 1, 2000 final rule (65 FR 47064).

a. Moving Procedure Codes From DRGs 468 or 477 to MDCs

We annually conduct a review of procedures producing assignment to DRG 468 or DRG 477 on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these DRGs into one of the surgical DRGs for the MDC into which the principal diagnosis falls. The data are arrayed two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

Our medical consultants identified those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical DRGs for the MDC in which the diagnosis falls. Based on this year's review, we did not identify any necessary changes in procedures under DRG 477 and, therefore, we did not propose to move any procedures from DRG 477 to one of the surgical DRGs. However, our medical consultants have identified a number of procedure codes that should be removed from DRG 468 and put into more clinically coherent DRGs. The movements of these codes are specified in the charts below:

MOVEMENT OF PROCEDURE CODES FROM DRG 468

Procedure code	Description	Included in DRG	Description
MDC 1—Diseases and Disorders of the Nervous System			
5495	Peritoneal Incision	7	Peripheral and Cranial Nerve and Other Nervous System Procedures with CC.
5495	Peritoneal Incision	8	Peripheral and Cranial Nerve and Other Nervous System Procedures without CC.
MDC 3—Diseases and Disorders of the Ear			
3821	Blood Vessel Biopsy	63	Other Ear, Nose, Mouth and Throat OR Procedure.
MDC 4—Diseases and Disorders of the Respiratory System			
3821	Blood Vessel Biopsy	76	Other Respiratory System OR Procedures with CC.

MOVEMENT OF PROCEDURE CODES FROM DRG 468—Continued

Procedure code	Description	Included in DRG	Description
3821	Blood Vessel Biopsy	77	Other Respiratory System OR Procedures with CC.
3929	Vascular Shunt & Bypass NEC	76	Other Respiratory System OR Procedures with CC.
3929	Vascular Shunt & Bypass NEC	77	Other Respiratory System OR Procedures with CC.
3931	Suture of Artery	76	Other Respiratory System OR Procedures with CC.
3931	Suture of Artery	77	Other Respiratory System OR Procedures with CC.
5411	Exploratory Laparotomy	76	Other Respiratory System OR Procedures with CC.
5411	Exploratory Laparotomy	77	Other Respiratory System OR Procedures with CC.
7749	Bone Biopsy NEC	76	Other Respiratory System OR Procedures with CC.
7749	Bone Biopsy NEC	77	Other Respiratory System OR Procedures with CC.
8669	Free Skin Graft NEC	76	Other Respiratory System OR Procedures with CC.
8669	Free Skin Graft NEC	77	Other Respiratory System OR Procedures with CC.
MDC 5—Diseases and Disorders of the Circulatory System			
3402	Exploratory Thoracotomy	120	Other Circulatory System OR Procedures.
3403	Reopen Thoractomy Site	120	Other Circulatory System OR Procedures.
3421	Transpleura Thoracoscopy	120	Other Circulatory System OR Procedures.
3422	Mediastinoscopy	120	Other Circulatory System OR Procedures.
3426	Open Mediastinal Biopsy	120	Other Circulatory System OR Procedures.
436	Distal Gastrectomy	120	Other Circulatory System OR Procedures.
437	Partial Gastrectomy with Jejunal Anastomosis	120	Other Circulatory System OR Procedures.
4389	Partial Gastrectomy	120	Other Circulatory System OR Procedures.
4399	Total Gastrectomy	120	Other Circulatory System OR Procedures.
4561	Multiple Segment Small Bowel Excision	120	Other Circulatory System OR Procedures.
4562	Partial Small Bowel Resection NEC	120	Other Circulatory System OR Procedures.
4572	Cecectomy	120	Other Circulatory System OR Procedures.
4573	Right Hemicolectomy	120	Other Circulatory System OR Procedures.
4574	Transverse Colon Resection	120	Other Circulatory System OR Procedures.
4575	Left Hemicolectomy	120	Other Circulatory System OR Procedures.
4579	Partial Large Bowel Excision NEC	120	Other Circulatory System OR Procedures.
458	Total Intra-Abdominal Colectomy	120	Other Circulatory System OR Procedures.
4593	Small-to-Large Bowel NEC	120	Other Circulatory System OR Procedures.
4603	Large Bowel Exteriorization	120	Other Circulatory System OR Procedures.
4613	Permanent Colostomy	120	Other Circulatory System OR Procedures.
4709	Other Appendectomy	120	Other Circulatory System OR Procedures.
4862	Anterior Rectal Resection With Colostomy	120	Other Circulatory System OR Procedures.
4863	Anterior Rectal Resection NEC	120	Other Circulatory System OR Procedures.
4869	Rectal Resection	120	Other Circulatory System OR Procedures.
5012	Open Liver Biopsy	120	Other Circulatory System OR Procedures.
540	Abdominal Wall Incision	120	Other Circulatory System OR Procedures.
MDC 6—Diseases and Disorders of the Digestive System			
5122	Cholecystectomy	170	Other Digestive System OR Procedures with CC.
5122	Cholecystectomy	171	Other Digestive System OR Procedures without CC.
5123	Laparoscopic Cholecystectomy	170	Other Digestive System OR Procedures with CC.
5132	GB-To-Intestine Anastomosis	170	Other Digestive System OR Procedures with CC.
5136	Choledochoenterostomy	170	Other Digestive System OR Procedures with CC.
5136	Choledochoenterostomy	171	Other Digestive System OR Procedures without CC.
5137	Hepatic Duct-GI Anastomosis	170	Other Digestive System OR Procedures with CC.
5137	Hepatic Duct-GI Anastomosis	171	Other Digestive System OR Procedures without CC.
5159	Bile Duct Incision NEC	170	Other Digestive System OR Procedures with CC.
5159	Bile Duct Incision NEC	171	Other Digestive System OR Procedures without CC.
MDC 7—Diseases and Disorders of the Hepatobiliary System and Pancreas			
540	Abdominal Wall Incision	201	Other Heptobiliary and Pancreas Procedure.
MDC 8—Diseases and Disorders of the Musculoskeletal System and Connective Tissue			
3479	Other Chest Wall Repair	233	Other Musculoskeletal System & Connective Tissue OR Procedure with CC.
3479	Other Chest Wall Repair	234	Other Musculoskeletal System & Connective Tissue OR Procedure with CC.
MDC 11—Diseases and Disorders of the Kideny and Urinary Tract			
540	Abdominal Wall Incision	315	Other Kidney & Urinary Tract OR Procedure.
5451	Laparoscopic Periton Adhesiolysis	315	Other Kidney & Urinary Tract OR Procedure.
5459	Other Periton Adhesiolysis	315	Other Kidney & Urinary Tract OR Procedure.

b. Reassignment of Procedures among DRGs 468, 476, and 477

We also annually review the list of ICD–9–CM procedures that, when in combination with their principal diagnosis code, result in assignment to DRGs 468, 476, and 477, to ascertain if any of those procedures should be moved from one of these DRGs to another of these DRGs based on average charges and length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting DRG assignment illogical. If our medical consultants were to find these shifts, we would propose moving cases to keep the DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data. Based on our review this year, we did not propose to move any procedures from DRG 468 to DRGs 476 or 477, from DRG 476 to DRGs 468 or 477, or from DRG 477 to DRGs 468 or 476.

c. Adding Diagnosis Codes to MDCs

Based on our review this year, we did not propose to add any diagnosis codes to MDCs.

We received one comment in support of the proposed changes to the procedure codes in DRG 468, 476, and 477. In this final rule, we are adopting these proposed changes without further modification.

12. Changes to the ICD–9–CM Coding System

As described in section II.B.1. of this preamble, the ICD–9–CM is a coding system that is used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the *Tabular List* and *Alphabetic Index for Diseases*, while CMS has lead responsibility for the ICD–9–CM procedure codes included in the *Tabular List* and *Alphabetic Index for Procedures.*

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA) (formerly American Medical Record Association (AMRA)), the American Hospital Association (AHA), and various physician specialty groups as well as physicians, medical record administrators, health information management professionals, and other members of the public to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2002 at public meetings held on May 11, 2000 and November 17, 2000, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 08, 2001.

Copies of the Coordination and Maintenance Committee minutes of the 2000 meetings can be obtained from the CMS home page at: http://www.hcfa.gov/medicare/icd9cm.htm. Paper copies of these minutes are no longer available and the mailing list has been discontinued. We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson; ICD–9–CM Coordination and Maintenance Committee; NCHS; Room 1100; 6525 Belcrest Road; Hyattsville, MD 20782. Comments may be sent by E-mail to: dfp4@cdc.gov.

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson; ICD–9–CM Coordination and Maintenance Committee; CMS, Center for Medicare Management, Purchasing Policy Group, Division of Acute Care; C4–07–07; 7500 Security Boulevard; Baltimore, MD 21244–1850. Comments may be sent by E-mail to: pbrooks@cms.hhs.gov.

The ICD–9–CM code changes that have been approved will become effective October 1, 2001. The new ICD–9–CM codes are listed, along with their DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively) in section V. of the Addendum to this final rule. As we stated above, the code numbers and their titles were presented for public comment at the ICD–9–CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved. In the proposed rule, we solicited comments only on the proposed DRG classification of these new codes.

Further, the Committee has approved the expansion of certain ICD–9–CM codes to require an additional digit for valid code assignment. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes). These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2001. For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A (New Diagnosis Codes). New procedure codes are shown in Table 6B. Table 6C contains invalid diagnosis codes, and Table 6D contains invalid procedure codes. Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which also include the DRG assignments for these revised codes. Revisions to procedure code titles are in Table 6F (Revised Procedure Codes Titles).

In September 2000, the Department implemented a policy of paying for inpatient hospital stays for Medicare beneficiaries participating in clinical trials (HCFA Program Memorandum AB 00–89, September 19, 2000). Hospitals were encouraged to identify the patients involved by reporting an ICD–9–CM code. This would allow the examination of data on the patients involved in clinical trials. However, there was no clear ICD–9–CM diagnosis code for patients who took part in a clinical trial. There was a code for patients receiving an examination as part of the control group for clinical trials. This control group code was V70.7 (Examination for normal comparison or control in clinical research). Hospitals were instructed to use V70.5 (Health examination of defined subpopulations), for patients participating in a clinical trial.

This coding directive has created some confusion because of the title and description of the two codes. Hospitals also have requested that all clinical patients be captured under one code. They indicated that the use of one code

would be especially useful because patients frequently do not know if they are part of the control group or are receiving new therapy.

To help alleviate the confusion, the ICD–9–CM Coordination and Maintenance Committee revised code V70.7. Effective October 1, 2001, the new title of code V70.7 is ''Examination of patient in clinical trial.'' This revision will make it easier to capture data on Medicare beneficiaries who are participating in a clinical trial.

Comment: One commenter questioned the DRG assignment of 525.12 (Loss of teeth due to periodontal disease) listed in Table 6A of the Addendum of the proposed rule. Table 6A in the proposed rule listed the proposed DRG assignments within MDC 3 for this new code as DRGs 182, 183, and 184. The commenter stated that the DRG assignments within MDC 3 should actually be DRGs 185, 186, and 187, since these were the DRGs used for its predecessor code, 525.1. The commenter also pointed out that the other new codes within this category (525.10–525.19) were assigned to DRGs 185, 186, and 187.

Response: The commenter is correct. We are assigning code 525.12 to DRGs 185, 186, and 187 within MDC 3. This is consistent with the way the other codes in the new category were assigned. In this final rule, we are correcting Table 6A to show that 525.12 is assigned to DRGs 185, 186, and 187 within MDC 3.

13. Other Issues

a. Pancreas Transplant

Effective July 1, 1999, Medicare covers whole organ pancreas transplantation if the transplantation is performed simultaneously with or after a kidney transplant (procedure codes 55.69 (Other kidney transplantation), or diagnosis code V42.0 (Organ or tissue replaced by transplant, Kidney), along with 52.80 (Pancreatic transplant, not otherwise specified), or 52.82 (Homotransplant of pancreas)). A discussion of the history of these coverage decisions and codes can be found in the August 1, 2000 final rule on the prospective payment system for FY 2001 (65 FR 47067).

We discussed the appropriate DRG classification for these cases in both the July 30, 1999 final rule (64 FR 41497) and the August 1, 2000 final rule (65 FR 47067). Currently, cases can be assigned to one of two major DRGs depending on principal diagnosis. If a kidney transplant and a pancreas transplant are performed simultaneously on a patient with chronic renal failure secondary to diabetes with renal manifestations (diagnosis codes 250.40 through 250.43), the cases will be assigned to DRG 302 (Kidney Transplant). If a pancreas transplant is performed following a kidney transplant (during a different hospital admission) on a patient with chronic renal failure secondary to diabetes with renal manifestations, the case is assigned to DRG 468 (Extensive OR Procedure Unrelated to Principal Diagnosis). This is because pancreas transplant is not assigned to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), the MDC to which a principal diagnosis of chronic renal failure secondary to diabetes is assigned.

In the August 1, 2000 final rule, we noted that we would continue to monitor these transplant cases to determine the appropriateness of establishing a new DRG. For the May 4 proposed rule, using data in the FY 2000 MedPAR file (updated through May 31, 2000), we analyzed the cases for which procedure codes 52.80 and 52.82 were reported. (Our data showed that 15 of the cases were coded using 52.83 (Heterotransplant of pancreas), which is not a covered procedure under any circumstances.) We identified a total of 221 cases for this time period. The United Network for Organ Sharing (UNOS) reported it had identified 270 cases through September 2000.

These 221 MedPAR cases were distributed over 6 DRGs, with the majority (158 cases or 72 percent) assigned to DRG 302, and 23 cases (10 percent) assigned to DRG 468. The remaining 40 cases were distributed between 4 other DRGs, with the majority (25 cases) being assigned to DRG 292 (Other Endocrine, Nutritional and Metabolic OR Procedures with CC). Four cases were assigned to DRG 483 (Tracheostomy with Principal Diagnosis except Face, Mouth and Neck Diagnoses) in the Pre-MDC grouping, which took precedence over any other DRG assignment.

We arrayed the data based on the presence or absence of kidney transplant; that is, pancreas transplant codes with or without 55.69. The majority of cases (166 or 75 percent) had the combined kidney-pancreas transplant in one operative episode, with 55 (25 percent) of the cases having pancreas transplant subsequent to the kidney transplant. Differences in hospital charges were significantly higher for a pancreas transplant plus a kidney transplant ($138,809) than a pancreas transplant alone ($85,972), and both were higher than average standardized charges in DRG 302 ($64,760) or DRG 468 ($39,707), although it must be noted that these figures do reflect the resource intensive patients assigned to DRG 483. Those patients in DRG 483 had average standardized charges of $377,934.

Because these categories of patients do not fit into existing DRGs from either a clinical or resource perspective, in the May 4 proposed rule, we proposed to create two new DRGs that would reflect these patients' unique clinical profiles: DRG 512 (Simultaneous Pancreas/Kidney Transplant) and DRG 513 (Pancreas Transplants). Cases grouped to either DRGs 512 or 513 must have a principal or secondary diagnosis code and procedure code or combination of procedure codes as indicated in the chart below:

COMPOSITION OF PROPOSED DRGS 512 AND 513

Diagnosis and procedure codes	Included in DRG 512	Included in DRG 513
Principal or Secondary ICD–9–CM Diabetes Mellitus Code:		
250.00 Diabetes mellitus without mention of complication, Type II or unspecified type, not as stated as uncontrolled	X	X
250.01 Diabetes mellitus without mention of complication, Type I, not stated as uncontrolled	X	X
250.02 Diabetes mellitus without mention of complication, Type II or unspecified type, uncontrolled	X	X
250.03 Diabetes mellitus without mention of complication, Type I, uncontrolled	X	X
250.10 Diabetes with ketoacidosis, Type II or Unspecified type, not stated as uncontrolled	X	X
250.11 Diabetes with ketoacidosis, Type I, not stated as uncontrolled	X	X
250.12 Diabetes with ketoacidosis, Type II or unspecified type, uncontrolled	X	X
250.13 Diabetes with ketoacidosis, Type I, controlled	X	X
250.20 Diabetes with hyperosmolarity, Type II or unspecified type, not stated as uncontrolled	X	X
250.21 Diabetes with hyperosmolarity, Type I, not stated as uncontrolled	X	X

COMPOSITION OF PROPOSED DRGS 512 AND 513—Continued

Diagnosis and procedure codes	Included in DRG 512	Included in DRG 513
250.22 Diabetes with hyperosmolarity, Type II or unspecified type, uncontrolled	X	X
250.23 Diabetes with hyperosmolarity, Type I, uncontrolled	X	X
250.30 Diabetes with other coma, Type II or unspecified type, not stated as uncontrolled	X	X
250.31 Diabetes with other coma, Type I, not stated as uncontrolled	X	X
250.32 Diabetes with other coma, Type II or unspecified type, uncontrolled	X	X
250.33 Diabetes with other coma, Type I, uncontrolled	X	X
250.40 Diabetes with renal manifestations, Type II or unspecified type, not stated as uncontrolled	X	X
250.41 Diabetes with renal manifestations, Type I, not stated as uncontrolled	X	X
250.42 Diabetes with renal manifestations, Type II or unspecified type, uncontrolled	X	X
250.43 Diabetes with renal manifestations, Type I, uncontrolled	X	X
250.50 Diabetes with ophthalmic manifestations, Type II or unspecified type, not stated as uncontrolled	X	X
250.51 Diabetes with ophthalmic manifestations, Type I, not stated as uncontrolled	X	X
250.52 Diabetes with ophthalmic manifestations, Type II or unspecified type, uncontrolled	X	X
250.53 Diabetes with ophthalmic manifestations, Type I, uncontrolled	X	X
250.60 Diabetes with neurological manifestations, Type II or unspecified type, not stated as uncontrolled	X	X
250.61 Diabetes with neurological manifestations, Type I, not stated as uncontrolled	X	X
250.62 Diabetes with neurological manifestations, Type II or unspecified type, uncontrolled	X	X
250.63 Diabetes with neurological manifestations, Type I uncontrolled	X	X
250.70 Diabetes with peripheral circulatory disorders, Type II or unspecified type, not stated as uncontrolled	X	X
250.71 Diabetes with peripheral circulatory disorders, Type I, not stated as uncontrolled	X	X
250.72 Diabetes with peripheral circulatory disorders, Type II or unspecified type, uncontrolled	X	X
250.73 Diabetes with peripheral circulatory disorders, Type I, uncontrolled	X	X
250.80 Diabetes with other specified manifestations, Type II or unspecified type, not stated as uncontrolled	X	X
250.81 Diabetes with other specified manifestations, Type I, not states as uncontrolled	X	X
250.82 Diabetes with other specified manifestations, Type II or unspecified type, uncontrolled	X	X
250.83 Diabetes with other specified manifestations, Type I, uncontrolled	X	X
250.90 Diabetes with unspecified complication, Type II or unspecified type, not states as uncontrolled	X	X
250.91 Diabetes with unspecified complication, Type I, not stated as uncontrolled	X	X
250.92 Diabetes with unspecified complication, Type II or unspecified type, uncontrolled	X	X
250.93 Diabetes with unspecified complication, Type I, uncontrolled	X	X
Principal or Secondary Diagnosis Code:		
585 Chronic renal failure.	X	X
403.01 Hypertensive renal disease, malignant, with renal failure	X	X
403.11 Hypertensive renal disease, benign, with renal failure	X	X
403.91 Hypertensive renal disease, unspecified, with renal failure	X	X
404.02 Hypertensive heart & renal disease, malignant, with renal failure	X	X
404.03 Hypertensive heart & renal disease, malignant, with congestive heart failure and renal disease	X	X
404.12 Hypertensive heart & renal disease, benign, with renal failure	X	X
404.13 Hypertensive heart & renal disease, benign, with congestive heart failure and renal disease	X	X
404.92 Hypertensive heart & renal disease, unspecified, with renal failure	X	X
404.93 Hypertensive heart & renal disease, unspecified, with congestive heart failure and renal failure	X	X
V42.0 Organ or tissue replaced by transplant, kidney	X	X
V43.89 Organ or tissue replaced by other means, other (Kidney)	X	X
Procedure Code:		
52.80 Pancreatic transplant, not otherwise specified	.....	X
52.82 Homotransplant of pancreas	.....	X
Combination Procedure Codes:		
52.80 Pancreatic transplant, not otherwise specified, **Plus** 55.69 Other kidney transplantation	X	.....
Or 52.82 Homotransplant of pancreas **Plus** 55.69 Other kidney transplantation	X	.....

The logic for the DRG 512 accepts the pair of diagnosis codes in any position (principal/secondary or secondary/secondary). The pair of procedure codes must be present along with the two diagnosis codes. This DRG will be placed in the Pre-MDC GROUPER logic immediately following DRG 480 (Liver Transplant).

The logic for DRG 513 accepts the pair of diagnosis codes in any position (principal/secondary or secondary/secondary). Only one procedure code must be used along with the two diagnosis codes. This DRG will be placed in the Pre-MDC GROUPER logic immediately following new DRG 512 (Simultaneous Pancreas/Kidney Transplant).

We received two comments on this proposal. One commenter supported the creation of the two new DRGs; a summary of the other comment follows:

Comment: One commenter noted that, as pancreas transplants were approved by Medicare on July 1, 1999, a special billing procedure should be made available to hospitals to enable hospitals to bill for the transplant DRG back to the effective date of the covered service.

Response: DRGs 512 and 513 are effective for discharges occurring on or

after October 1, 2001, for FY 2002. Discharges involving pancreas transplants occurring prior to that time are assigned to existing DRGs as described above. Therefore, there is no need for hospitals to resubmit their bills.

We are adopting the establishment of proposed DRGs 512 and 513 as final.

b. Intestinal Transplantation

Effective April 1, 2001, Medicare covers intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure (Medicare Program Memorandum Transmittal No. AB–01–58, April 12, 2001). This procedure is covered only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria.

Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. Intestinal failure prevents oral nutrition and may be associated with both mortality and profound morbidity.

If an intestinal transplantation alone is performed on a patient with an intestinal principal diagnosis, the case would be assigned to either DRG 148 (Major Small & Large Bowel Procedures With CC) or DRG 149 (Major Small & Large Bowel Procedures Without CC). If an intestinal transplantation and a liver transplantation are performed simultaneously, the case would be assigned to DRG 480 (Liver Transplant).

If an intestinal transplantation alone is performed on a patient with an intestinal principal diagnosis, the case would be assigned to either DRG 148 (Major Small & Large Bowel Procedures with CC) or DRG 149 (Major Small & Large Bowel Procedures Without CC). If an intestinal transplantation and a liver transplantation are performed simultaneously, the case would be assigned to DRG 480 (Liver Transplant).

If an intestinal transplantation and a pancreas transplantation are performed simultaneously, currently the case would be assigned to either DRG 148 or DRG 149. Effective October 1, 2001, the case would be assigned to DRG 513 (Pancreas Transplant). We proposed to make a conforming change to the regulations at § 412.2(e)(4) and § 486.302 to include intestines (and multivisceral organs) in the list of organs for which Medicare pays for the acquisition costs on a reasonable cost basis.

Effective October 1, 2000, procedure code 46.97 (Transplant of intestine) was created. For the proposed rule, we examined our Medicare claims data to determine whether it was appropriate to propose a new intestinal transplant DRG. We examined data in the FY 2000 MedPAR file containing bills submitted through May 31, 2000. Because procedure code 46.97 was not in place during this time we focused our examination on the previous code assignment for intestinal transplant, code 46.99 (Other operations on intestines), and facilities that are currently performing intestinal transplantation. We were able to identify only one case, with an average charge of approximately $10,738 as compared to the average standardized charges for DRGs 148 and 149, which are approximately $37,961, and $16,965, respectively. We will continue to monitor these cases to determine whether it may be appropriate in the future to establish a new DRG.

Comment: One commenter recommended performing data analysis next year to determine if a separate intestinal transplantation DRG should be created based on the fact that these procedures are being performed on a more frequent basis. Another commenter suggested that the preamble specifically state that while the acquisition costs for heart, liver, lung, and pancreas transplants continue to be paid on a reasonable cost basis, the acquisition costs for intestinal transplantation will be paid through the hospital inpatient prospective payment system DRG payment mechanism.

Response: It is our intent to continue to monitor these cases to determine whether it may be appropriate in the future to establish a new DRG.

To clarify the issue of acquisition costs, Medicare Program Memorandum Transmittal No. AB–01–58, released April 12, 2001, states that Medicare will not pay transplant facilities on a reasonable cost basis for organ acquisition for intestinal or multivisceral transplants. The DRG payment will be payment in full for hospital services related to this procedure. However, in this final rule, we are implementing a conforming change to the regulations at § 412.2(e)(4) and § 486.302, to include intestines (and multivisceral organs) in the list of organs for which Medicare pays for the acquisition costs on a reasonable cost basis. This change is effective with acquisition costs incurred on or after October 1, 2001. After that date, costs associated with the acquisition of intestines and multivisceral organs will be paid on a reasonable cost basis. Costs associated with intestines procured separately will be allocated to an intestine cost center and allocated on Worksheet D–6. Multivisceral organ transplantation includes organs in the digestive system (that is, stomach, duodenum, pancreas, liver, intestine, and colon). Multivisceral procurements, including an organ(s) as defined at § 486.302 as well as the intestine (small bowel), will be allocated to the intestinal acquisition cost center. Multivisceral procurements are procured en bloc and the entire cost of procuring all of the organs will be allocated to the intestinal acquisition cost center.

c. Payment for Blood Clotting Factor Administered to Hemophilia Inpatients

Comment: Although this issue was not addressed in the proposed rule, we received one comment requesting that the add-on payment for blood clotting factors administered to hemophilia inpatients include adequate reimbursement for hospitals that treat beneficiaries with acquired hemophilia.

Response: According to section 4452 of Public Law 105–33, which amended section 6011(d) of Public Law 101–239, prospective payment hospitals receive an additional payment for costs of administering blood clotting factor to Medicare hemophiliacs who are hospital inpatients.

Hemophilia, a bleeding disorder characterized by prolonged clotting time, is caused by a deficiency of a factor necessary for blood to clot. In the August 29, 1997 final rule implementing section 4452 of Public Law 105–33 (62 FR 46002), we stated that hemophilia was considered to encompass the following conditions: Factor VIII deficiency (classical hemophilia); Factor IX deficiency (also termed plasma thromboplastin component (PTC) or Christmas factor deficiency); and Von Willebrand's disease. The most common factors required by hemophiliacs to increase coagulation are Factor VIII and Factor IX; a small number of hemophiliacs have developed inhibitors to these factors and require special treatment. We did not receive any comments regarding this coverage until, most recently, the cases of acquired hemophilia, which affects a small subset of individuals (1 in 1 million), were brought to our attention.

We are revising our claims processing instructions to permit add-on payments for the following ICD–9–CM diagnosis codes associated with acquired hemophilia:

286.5 Hemorrhagic disorder due to circulating anticoagulants

286.7 Acquired coagulation factor deficiency.

C. Recalibration of DRG Weights

We proposed to use the same basic methodology for the FY 2002 recalibration as we did for FY 2001 (August 1, 2000 final rule (65 FR 47069)). That is, we would recalibrate the weights based on charge data for Medicare discharges. However, we proposed to use the most current charge information available, the FY 2000 MedPAR file. (For the FY 2001 recalibration, we used the FY 1999 MedPAR file.) The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills.

The final recalibrated DRG relative weights are constructed from FY 2000 MedPAR data (discharges occurring between October 1, 1999 and September 30, 2000), based on bills received by CMS through March 31, 2001, from all hospitals subject to the prospective payment system and short-term acute care hospitals in waiver States. The FY 2000 MedPAR file includes data for approximately 11,094,323 Medicare discharges.

The methodology used to calculate the DRG relative weights from the FY 2000 MedPAR file is as follows:

- To the extent possible, all the claims were regrouped using the DRG classification revisions discussed in section II.B. of this preamble.
- Charges were standardized to remove the effects of differences in area wage levels, indirect medical education and disproportionate share payments, and, for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment.
- The average standardized charge per DRG was calculated by summing the standardized charges for all cases in the DRG and dividing that amount by the number of cases classified in the DRG.
- We then eliminated statistical outliers, using the same criteria used in computing the current weights. That is, all cases that are outside of 3.0 standard deviations from the mean of the log distribution of both the charges per case and the charges per day for each DRG are eliminated.
- The average charge for each DRG was then recomputed (excluding the statistical outliers) and divided by the national average standardized charge per case to determine the relative weight. A transfer case is counted as a fraction of a case based on the ratio of its transfer payment under the per diem payment methodology to the full DRG payment for nontransfer cases. That is, transfer cases paid under the transfer methodology equal to half of what the case would receive as a nontransfer would be counted as 0.5 of a total case.
- We established the relative weight for heart and heart-lung, liver, and lung transplants (DRGs 103, 480, and 495) in a manner consistent with the methodology for all other DRGs except that the transplant cases that were used to establish the weights were limited to those Medicare-approved heart, heart-lung, liver, and lung transplant centers that have cases in the FY 1999 MedPAR file. (Medicare coverage for heart, heart-lung, liver, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Acquisition costs for kidney, heart, heart-lung, liver, lung, and pancreas transplants continue to be paid on a reasonable cost basis. Unlike other excluded costs, the acquisition costs are concentrated in specific DRGs: DRG 302 (Kidney Transplant); DRG 103 (Heart Transplant); DRG 480 (Liver Transplant); DRG 495 (Lung Transplant); and proposed new DRGs 512 (Simultaneous Pancreas/Kidney Transplant) and 513 (Pancreas Transplant). Because these costs are paid separately from the prospective payment rate, it is necessary to make an adjustment to prevent the relative weights for these DRGs from including the acquisition costs. Therefore, we subtracted the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average charge for the DRG and before eliminating statistical outliers.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We use that same case threshold in recalibrating the DRG weights for FY 2002. Using the FY 2000 MedPAR data set, there are 37 DRGs that contain fewer than 10 cases. We computed the weights for these 37 low-volume DRGs by adjusting the FY 2001 weights of these DRGs by the percentage change in the average weight of the cases in the other DRGs.

The new weights are normalized by an adjustment factor (1.44556) so that the average case weight after recalibration is equal to the average case weight before recalibration. This adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the prospective payment system, and accounts for the gradual shift in cases toward higher-weighted DRGs over time.

We received no comments on DRG recalibration.

Section 1886(d)(4)(C)(iii) of the Act requires that, beginning with FY 1991, reclassification and recalibration changes be made in a manner that assures that the aggregate payments are neither greater than nor less than the aggregate payments that would have been made without the changes. Although normalization is intended to achieve this effect, equating the average case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payment to hospitals is affected by factors other than average case weight. Therefore, as we have done in past years and as discussed in section II.A.4.a. of the Addendum to the final rule, we make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

III. Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts ''for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.'' In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by the Office of Management and Budget (OMB). The OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs since they allow a more precise breakdown of labor costs. If a metropolitan area is not designated as part of a PMSA, we use the applicable MSA. Rural areas are areas outside a designated MSA, PMSA, or NECMA. For purposes of the wage index, we combine all of the rural counties in a State to calculate a rural wage index for that State.

We note that, effective April 1, 1990, the term Metropolitan Area (MA) replaced the term MSA (which had been used since June 30, 1983) to describe the set of metropolitan areas consisting of MSAs, PMSAs, and CMSAs. The terminology was changed by OMB in

the March 30, 1990 **Federal Register** to distinguish between the individual metropolitan areas known as MSAs and the set of all metropolitan areas (MSAs, PMSAs, and CMSAs) (55 FR 12154). For purposes of the prospective payment system, we will continue to refer to these areas as MSAs.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey should measure, to the extent feasible, the earnings and paid hours of employment by occupational category, and must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. As discussed below in section III.F. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating the wage index.

B. FY 2002 Wage Index Update

The FY 2002 wage index values in section V of the Addendum to this final rule (effective for hospital discharges occurring on or after October 1, 2001 and before October 1, 2002) are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 1998 (the FY 2001 wage index was based on FY 1997 wage data).

The final FY 2002 wage index includes the following categories of data associated with costs paid under the hospital inpatient prospective payment system (as well as outpatient costs), which were also included in the FY 2001 wage index:

- Salaries and hours from short-term, acute care hospitals.
- Home office costs and hours.
- Certain contract labor costs and hours.
- Wage-related costs.

Consistent with the wage index methodology for FY 2001, the wage index for FY 2002 also continues to exclude the direct and overhead salaries and hours for services not paid through the inpatient prospective payment system such as skilled nursing facility (SNF) services, home health services, or other subprovider components that are not subject to the prospective payment system.

We calculate a separate Puerto Rico-specific wage index and apply it to the Puerto Rico standardized amount. (See 62 FR 45984 and 46041.) This wage index is based solely on Puerto Rico's data. Finally, section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State.

C. FY 2002 Wage Index

Because the hospital wage index is used to adjust payments to hospitals under the prospective payment system, the wage index should, to the extent possible, reflect the wage costs associated with the areas of the hospital included under the hospital inpatient prospective payment system. In response to concerns within the hospital community related to the removal, from the wage index calculation, of costs related to graduate medical education (GME) (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), which are paid by Medicare separately from the prospective payment system, the AHA convened a workgroup to develop a consensus recommendation on this issue. The workgroup recommended that costs related to GME and CRNAs be phased out of the wage index calculation over a 5-year period. Based upon our analysis of hospitals' FY 1996 wage data, and consistent with the AHA workgroup's recommendation, we specified in the July 30, 1999 final rule (64 FR 41505) that we would phase-out these costs from the calculation of the wage index over a 5-year period, beginning in FY 2000. In keeping with the decision to phase-out costs related to GME and CRNAs, the final FY 2002 wage index is based on a blend of 40 percent of an average hourly wage including these costs, and 60 percent of an average hourly wage excluding these costs.

Beginning with the FY 1998 cost reports, we revised the Worksheet S–3, Part II so that hospitals can separately report teaching physician Part A costs on lines 4.01, 10.01, 12.01, and 18.01. Therefore, it is no longer necessary for us to conduct the special survey we used for the FY 2000 and FY 2001 wage indexes (64 FR 41505 and 65 FR 47071).

1. Health Insurance and Health-Related Costs

In the August 1, 2000 final rule, we clarified our definition of ''purchased health insurance costs'' and ''self-insurance'' for hospitals that provide health insurance to employees (65 FR 47073). For purposes of the wage index, purchased or self-funded health insurance plan costs include the hospitals' insurance premium costs, external administration costs, and the share of costs for services delivered to employees.

In response to a comment received concerning this issue, we stated that, for self-funded health insurance costs, personnel costs associated with hospital staff that deliver the services to the employees must continue to be excluded from wage-related costs if the costs are already included in the wage data as salaries on Worksheet S–3, Part II, Line 1. However, after further consideration of this policy, particularly with respect to concerns expressed by our fiscal intermediaries about the level of effort required during the wage index desk review process to ensure hospitals are appropriately identifying and excluding these costs, in the May 4, 2001 proposed rule we proposed a revision. Effective with the calculation of the FY 2003 wage index, for either purchased or self-funded health insurance, we proposed to allow personnel costs associated with hospital staff who deliver services to employees to be included as part of the wage-related costs. We believe the proposed revised policy will ensure that health insurance costs are consistently reported by hospitals. Health insurance costs would continue to be developed using generally accepted accounting principles.

In the August 1, 2000 final rule (65 FR 47073), we further clarified that health-related costs (including employee physical examinations, flu shots, and clinic visits, and other services that are not covered by employees' health insurance plans but are provided at no cost or at discounted rates to employees of the hospital) may be included as ''other'' wage-related costs if, among other criteria, the combined cost of all such health-related costs is greater than one percent of the hospital's total salaries (less excluded area salaries).

For purposes of calculating the FY 2003 wage index (which will be based on data for cost reporting periods beginning in FY 1999), we proposed to revise this policy to allow hospitals to include health-related costs as allowable core wage-related costs.

Comment: One commenter supported our proposal to include health-related costs as core wage-related costs. The commenter also agreed with our proposal to include all personnel costs associated with hospital staff who deliver health services to employees. However, the commenter expressed concern that the proposed changes would require burdensome and duplicative revisions to cost reports that have already been filed.

Response: We believe that these revised policies (to eliminate the

distinction between purchased health insurance and self-funded health insurance, and to treat costs associated with health-related services that are not part of the employees' health insurance plan consistent with costs included in the plan) will ensure that these costs are treated consistently across hospitals and fiscal intermediaries.

In response to the commenter's concern that the policy will require revisions to previously submitted cost reports, we believe the changes are not significant, particularly in light of the volume of changes submitted every year by hospitals during the wage data review process (see discussion in section III.G. of this final rule). The cost report changes necessary to implement these policy changes involve including costs previously disallowed. In the case of personnel costs associated with hospital staff who deliver services to employees, these costs would have already been identified in order to be excluded from the wage data. With respect to health services provided outside the employees' health insurance plan, we acknowledge that some hospitals may not have tracked these costs because they did not qualify for inclusion as other wage-related costs. However, due to concerns expressed by fiscal intermediaries about the difficulty of identifying these costs separate from those that are part of the insurance plan, we believe there may be inconsistencies in the current data with regard to how these costs are treated. Therefore, we believe, in the interest of improving the consistency of the data, that we should begin to allow these costs as core wage-related costs effective with the FY 2003 wage index.

2. Costs of Contracted Pharmacy and Laboratory Services

Our policy concerning inclusion of contract labor costs for purposes of calculating the wage index has evolved over the years. We recognize the role of contract labor in meeting special personnel needs of many hospitals. In addition, improvements in the wage data have allowed us to more accurately identify contract labor costs and hours. As a result, effective with the FY 1994 wage index, we included the costs of direct patient care contract services in the wage index calculation. The FY 1999 wage index included the costs and hours of certain management contract services, and the FY 2000 wage index included the costs for contract physician Part A services. (The 1996 proposed rule (61 FR 27456) provided an in-depth background to the issues related to the inclusion of contract labor costs in the wage index calculation.)

We revised the 1998 cost report to collect the data associated with contract pharmacy, Worksheet S–3, Part II, Line 9.01, and contract laboratory, Worksheet S–3, Part II, Line 9.02. The cost reporting instructions for these line numbers followed that for all contract labor lines; that is, to include the amount paid for services furnished under contract for direct patient care, and not include cost for equipment, supplies, travel expenses, and other miscellaneous or overhead items (Medicare Provider Reimbursement Manual, Part 2, Cost Reporting Forms and Instructions, Chapter 36, Transmittal 6, pages 36–32). Effective with the FY 2002 wage index, which uses FY 1998 wage data, we are including in this final rule (as proposed in the May 4 proposed rule) the costs and hours of contract pharmacy and laboratory services.

Comment: Two commenters supported our proposed policy to include the costs and hours of contract pharmacy and laboratory as direct patient care contract labor in the FY 2002 wage index. However, both commenters recommended that clearer guidelines be provided to ensure consistency in interpretation by fiscal intermediaries and contract vendors.

Response: Beginning with the FY 2002 wage index, we are including the costs and hours of contract pharmacy and laboratory services in the calculation of the wage index. Further instructions for reporting contract pharmacy and laboratory costs will be included in Transmittal 8 of the cost report, due for release in early fall 2001.

3. Collection of Occupational Mix Data

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require that the Secretary must provide for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. The initial collection of these data must be completed by September 30, 2003, for application beginning October 1, 2004.

Currently, the wage data collected on the cost report reflect the sum of wages, hours, and wage-related costs for all hospital employees. There is no separate collection by occupational categories of employees, such as registered nurses or physical therapists. Total salaries and hours reflect management decisions made by hospitals in terms of how many employees within a certain occupation to employ to treat different types of patients. For example, a large academic medical center may tend to hire more high-cost specialized employees to treat its more acutely ill patient population. The argument is that the higher labor costs incurred to treat this patient population are reflected in the higher case mix of these hospitals, and therefore, reflecting these costs in the wage index is essentially counting them twice.

An occupational mix adjustment can be used to account for hospital management decisions about how many employees to hire in each occupational category. Occupational mix data measure the price the hospital must pay for employees within each category. A wage index that reflected only these market prices would remove the impact of management decisions about the mix of employees needed and, therefore, better capture geographic variations in the labor market.

We have examined this issue previously. In the May 27, 1994 **Federal Register** (59 FR 27724), we discussed the outcome of consideration of this issue by a hospital workgroup. At that time, the workgroup's consensus was that the data required to implement an occupational mix adjustment were not available and the likelihood of obtaining such data would be minimal. There seemed to be little support among hospital industry representatives for developing a system that would create additional reporting burdens with an unproven or minimal impact on the distribution of payments. Also, in the August 30, 1991 **Federal Register** (56 FR 43219), we stated our belief that the collection of these data would be costly and difficult.

In considering the format to collect occupational mix data, we looked to data currently being collected by the Bureau of Labor Statistics (BLS), which conducts an annual mail survey to produce estimates of employment and wages for specific occupations. This program, Occupational Employment Statistics (OES), collects data on wage and salary workers in nonfarm establishments in order to produce employment and wage estimates for over 700 occupations.

The OES survey collects wage data in 12 hourly rate intervals. Employers report the number of employees in an occupation per each wage range. To illustrate, the wage intervals used for the 1999 survey are as follows:

Interval	Hourly wages	Annual wages
Range A	Under $6.75	Under $14,040.
Range B	$6.75 to $8.49	$14,040 to $17,659.
Range C	8.50 to 10.74	17,660 to 22,359.
Range D	10.75 to 13.49	22,360 to 28,079.
Range E	13.50 to 16.99	28,080 to 35,359.
Range F	17.00 to 21.49	35,360 to 44,719.
Range G	21.50 to 27.24	44,720 to 56,679.
Range H	27.25 to 34.49	56,680 to 71,759.
Range I	34.50 to 43.74	71,760 to 90,999.
Range J	43.75 to 55.49	91,000 to 115,439.
Range K	55.50 to 69.99	115,440 to 145,599.
Range L	70.00 and over	145,600 and over.

We noted that this table is for illustrative purposes, and that we may update the data ranges in our actual collection instrument.

Although we initially considered using the OES data, section 304(c) of Public Law 106–554 requires us to collect data from every short-term, acute care hospital. The OES data are a sample survey and, therefore, as currently conducted, are not consistent with the statutory requirement to include data from every hospital. Another issue with using OES data is that, for purposes of the Medicare wage index, the hospitals' data must be reviewed and verified by the fiscal intermediaries. The OES survey is a voluntary survey for most States.

Although we decided to pursue a separate data collection effort than OES, we proposed in the May 4, 2001 proposed rule to model our format after the one used by OES. In this way, hospitals participating in the OES survey would have no additional recordkeeping and reporting requirements beyond those of the OES survey.

The OES survey of the hospital industry is designed to capture all occupational categories within the industry. For purposes of adjusting the wage index for occupational mix, we do not believe it is necessary to collect data from such a comprehensive scope of categories. Furthermore, because the data must be audited, a comprehensive list of categories would be excessively burdensome.

In deciding which occupational categories to include, we reviewed the occupational categories collected by OES and identified those with at least 35,000 hospital employees. Our goal is to collect data from a sample of occupational categories that provides a valid measure of wage rates within a geographical area. In the May 4 proposed rule, using this threshold of at least 35,000 employees within a category nationally, we proposed to collect data on the number of employees by wage range as illustrated in the above table, for the occupational categories listed below. The following data, which was also listed in the proposed rule, are based on the 1998 OES survey. (These data are no longer available on the internet.)

OES code	Category	Number of employees	Percent of total hospital employees	Mean hourly wage
15008	Medicine and Health Services Manager	93,680	1.9	$27.38
27302	Social Workers, Medical and Psychiatric	53,360	1.1	16.33
32102	Physicians and Surgeons	125,640	2.6	43.76
32308	Physical Therapists	39,840	0.8	26.14
32502	Registered Nurses	1,231,980	25.0	21.12
32505	Licensed Practical Nurses	206,360	4.2	13.39
32517	Pharmacists	46,860	1.0	28.62
32911, 32928, and 32931	Clinical Technologists and Technicians	122,380	2.50	11.69
51002, 55105, 55108, 55305, 55332, and 55347.	First-Line Supervisors and Clerical Workers	445,730	9.5	11.39
65038, 67002, and 67005	Food Preparation Workers and Housekeeping	218,440	4.5	8.17
66008	Nursing Aides, Orderlies, and Attendants	301,240	6.2	8.67

We proposed that this list of occupational categories provides a good representation of the employee mix at most hospitals. It has since come to our attention that the occupational categories listed in the proposed rule have been replaced by Standard Occupational Category definitions.

Because we had not yet settled on the methodology to use the occupational mix data in the wage index, we discussed in the proposed rule one option to weight each hospital's wage index by its occupational mix index. This requires calculating a national occupational mix index and then breaking it down by MSA and by hospital, similar to how the wage index is broken down. In this way, the wage index would capture geographic differences in wage rates. The decision about how to apply the occupational mix index to the wage index depends on the quality of the data collected, since this effort will be the first time wage and hour data by occupation are collected in this audited manner.

Section 304(c) directs the Secretary to provide for the collection of these data by September 30, 2003, and to apply them in the wage index by October 1, 2004. Therefore, the data are to be incorporated in the FY 2005 wage index. Under our current timetable, the FY 2005 wage index will be based on wage data collected from hospitals' cost reporting periods beginning during FY 2001. In order to facilitate the fiscal intermediaries' review of these data, we believe the occupational mix data should coincide with the data otherwise

used to calculate the cost report. Therefore, we will conduct a special survey of all short-term acute-care hospitals that are required to report wage data to collect these data coinciding with hospitals' FY 2001 cost reports.

Comment: Several commenters expressed interest in working with us to develop an appropriate data collection tool. They suggested that the data be relatively simple for hospitals to gather and submit, and should be collected on 100 percent of hospital employees. Another commenter recommended that, at least initially, only data on nursing categories would be sufficient since nurses are 35 percent of hospital employees and can be divided into a few easily distinguishable categories. Two commenters offered examples for how these data are collected in their area. Some commenters wanted these data incorporated in the cost report to limit the number of forms hospitals must complete and to improve the response rate.

Response: We agree that it would be beneficial to work with the industry to develop a workable data collection tool, especially given the importance of the wage index in adjusting hospital payments. We appreciate the comments on the option presented in the proposed rule and believe that these comments will help initiate further thought toward the development of an occupational mix survey that can be administered without excessive burden on hospitals, the fiscal intermediaries, or CMS.

Due to time constraints in meeting the statutory deadlines, our intention at this point is to attempt to develop a survey instrument for the initial collection of occupational mix data that can be used by hospitals during calendar year 2002. Therefore, prior to January 1, 2002, we plan to work with the hospital community to develop a survey instrument. We believe issues related to the sample size of the data collected and the appropriate occupational categories to collect can best be resolved through consultation with the industry. Therefore, we will be contacting those organizations that expressed an interest in consultation in their comments. Other interested parties are encouraged to contact us as well.

After developing a method that appropriately balances the need to collect accurate and reliable data with the need to collect data hospitals can be reasonably expected to have available, we will issue instructions as to the type of data to be collected, in advance of actually requiring hospitals to begin providing the data.

Comment: Some commenters asked us to further develop the planned use of the occupation information and then decide what information is required. They requested that we publish the projected economic effects of an occupational mix adjustment upon each hospital as soon as feasible, and demonstrate tangible benefits prior to requiring hospitals to collect data. One commenter offered a specific methodology that could be employed. Other commenters want the methodology phased-in over time to allow hospitals time to adjust to different payment levels.

Response: In the proposed rule, we stated that we had not yet settled on the actual methodology for using the occupational mix data in the calculation of the wage index. We indicated the decision as to how the data will be used is dependent on the quality of the data collected. That is still the case. Furthermore, as discussed above, we intend to develop an appropriate data collection instrument in consultation with the hospital community. Therefore, until decisions are made with regard to the specific data to be collected, we cannot specify how the data will be used. However, the selection of an appropriate methodology (including a possible phase-in) will be influenced by analysis of the impacts of the method on hospital payments.

Comment: Two commenters expressed concerns that adopting the occupational mix adjustment for the wage index will lower the average hourly wage of teaching hospitals because of their mix of highly skilled, higher paid employees to treat patients with more complex conditions. These commenters argued that implementation of the occupational mix adjustment should proceed only in conjunction with the adoption of severity-adjusted DRGs. These commenters wrote that the current DRG system does not adequately recognize patient severity and pay for the higher resource costs associated with complex patients, but teaching hospitals can recoup some of these losses because their higher employee skill mix is reflected in their average hourly wage.

Furthermore, one commenter countered the argument that the higher labor costs incurred to treat a more severely ill patient population are reflected in the higher case mix of these hospitals and, therefore, reflecting these costs in the wage index is essentially counting them twice. This commenter pointed out that, because the DRG weights are based on hospital charges that are standardized by, among other factors, the area wage index, the weights of tertiary care DRGs are lower than they would be if the average charge per case were not first standardized by the wage index. However, the commenter went on to state that it is preferable to account for skill mix in the wage index rather than the case-mix index.

Response: As we stated in the August 1, 2000 final rule (65 FR 47103), we agree that severity-adjusted DRGs have potential for reducing discrepancies between payments and costs for individual cases (60 FR 29246). We have stated that, prior to implementing severity-adjusted DRGs, we would need specific legislative authority to offset any significant anticipated increase in payments attributable to changes in coding practices caused by significant changes to the DRG classification system. Section 301 of Public Law 106–554 authorized the Secretary to adjust the average standardized amounts if he determines that DRG coding or classification changes are likely to result in a change in aggregate payments. Therefore, based on this authority, we are beginning to evaluate the potential for implementing severity-adjusted DRGs. Because we are at the initial stages of that effort, we cannot yet estimate when, or if, such implementation may occur. However, we agree with these commenters' points that significant changes to any of the adjustments under the prospective payment system must be considered in light of the effects such changes may have to other such adjustments.

Comment: One commenter interpreted our proposal to suggest that the fiscal year for which the data will be collected will be closed by the time the methodology and data requirements have been established.

Response: In the proposed rule, we indicated we would conduct a special survey to collect these data to coincide with hospitals' cost reports beginning during FY 2001. We do not intend to require hospitals to retroactively adjust their payroll records to collect these data. Therefore, given our intention to gather input from the industry prior to designing the survey instrument, it likely will not be possible to completely coincide the data collection period with hospitals' FY 2001 cost reports.

Although there may be some auditing benefits to having the data overlap, this type of data is not routinely collected through the cost reports, so that the auditing benefits of such overlap may be minimal. In addition, there may be a benefit to collecting occupational mix for a more recent period in terms of reflecting current trends, such as higher wages paid to nurses during a shortage.

Comment: Other commenters raised specific technical concerns about the occupational mix discussion in the proposed rule.

Response: Rather than respond individually at this time to technical issues associated with the occupational mix discussion in the proposed rule, we will address these issues through direct consultation with the industry, as described above.

D. Verification of Wage Data From the Medicare Cost Report

The data for the FY 2002 wage index were obtained from Worksheet S–3, Parts II and III of the FY 1998 Medicare cost reports. The data file used to construct the wage index includes FY 1998 data submitted to us as of July 2001. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries to revise or verify data elements that resulted in specific edit failures. The unresolved data elements that were included in the calculation of the proposed FY 2002 wage index have been resolved and are reflected in the calculation of the final FY 2002 wage index. We note that, as part of this process to identify aberrant data and correct any errors prior to the calculation of the final FY 2002 wage index, we notified by letter those hospitals that were leading to large variations in the wage indexes of their labor market areas compared to the FY 2001 wage index. These hospitals were advised to review their data to identify the reason for the large increases or decreases and notify their fiscal intermediary of any necessary corrections.

Also, as part of our editing process, in the final wage index, we removed data for 30 hospitals that failed edits. For 24 of these hospitals, we were unable to obtain sufficient documentation to verify or revise the data because the hospitals are no longer participating in the Medicare program or are in bankruptcy status. Six hospitals had incomplete or inaccurate data resulting in exceptionally large, zero, or negative average hourly wages. Therefore, they were removed from the calculation. As a result, the final FY 2002 wage index is calculated based on FY 1998 wage data for 4,880 hospitals.

Comment: One commenter recommended that we incorporate additional fatal edits in the cost reporting systems to eliminate obvious errors on the Worksheet S–3 that result in incomplete or erroneous wage data that are difficult to correct 4 years later.

Response: We do not agree with the recommendation of the commenter. A separate desk review is performed for the wage index. The desk review, combined with the level two edits, is sufficient to provide fiscal intermediaries with information to identify discrepancies, such as zero or negative average hourly wage or missing hours, that can be resolved by the fiscal intermediary during the cost reporting process.

E. Computation of the FY 2002 Wage Index

We note a technical change to the FY 2002 calculation. For the FY 2001 wage index calculation, we initially proposed to subtract Line 13 of Worksheet S–3, Part III from total hours when determining the excluded hours ratio used to estimate the amount of overhead attributed to excluded areas (65 FR 26299). However, the formula resulted in large and inappropriate increases in the average hourly wages for some hospitals (65 FR 47074), particularly hospitals that have large overhead and excluded area costs. Therefore, for the final FY 2001 wage index calculation, we reverted to the FY 2000 excluded hours ratio formula, which did not subtract Line 13.

Subsequently, we analyzed how the application of this formula resulted in overstated average hourly wages for some hospitals and how we could improve the overall accuracy of the overhead allocation methodology. We became aware that the problem was not in the excluded hours ratio formula. Rather, our wage index calculation did not also remove the overhead wage-related costs associated with excluded areas, an amount that must be estimated before it can be subtracted from the calculation. The combined effect of applying the excluded hours ratio formula, which appropriately removes salaries of lower-wage, overhead employees, and not subtracting overhead wage-related costs associated with excluded areas, resulted in overstated salary costs and average hourly wages.

For the FY 2002 wage index calculation, we are applying the excluded hours ratio formula that subtracts Part III, Line 13 from total hours. Additionally, for the first time in the wage index calculation, we estimated and subtracted overhead wage-related costs allocated to excluded areas.

After we applied this new calculation, there were still a few hospitals that experienced large increases in their average hourly wages. The intermediaries verified that the hospitals' wage data were accurate, so we kept the data in the wage index calculation. These hospitals primarily function as SNFs, psychiatric hospitals, or rehabilitation hospitals that have few acute care beds. The hospitals' higher average hourly wages reflect the costs of the higher salaried employees that remain in the wage index calculation after we subtract the costs of excluded area and associated overhead employees.

The method used to compute the final FY 2002 wage index follows.

Step 1—As noted above, we based the FY 2002 wage index on wage data reported on the FY 1998 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 1997 and before October 1, 1998. In addition, we included data from any hospital that had cost reporting periods beginning before October 1997 and reported a cost reporting period covering all of FY 1998. These data were included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 1998 data. We note that, if a hospital had more than one cost reporting period beginning during FY 1998 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 1997 and before October 1, 1998), we included wage data from only one of the cost reporting periods, the longest, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the latest period in the wage index calculation.

Step 2—Salaries—The method used to compute a hospital's average hourly wage is a blend of 40 percent of the hospital's average hourly wage including all GME and CRNA costs, and 60 percent of the hospital's average hourly wage after eliminating all GME and CRNA costs.

In calculating a hospital's average salaries plus wage-related costs, including all GME and CRNA costs, we subtracted from Line 1 (total salaries) the Part B salaries reported on Lines 3 and 5, home office salaries reported on Line 7, and excluded salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to skilled nursing facility services, home health services, and other subprovider components not

subject to the inpatient prospective payment system). We also subtracted from Line 1 the salaries for which no hours were reported on Lines 2, 4, and 6. To determine total salaries plus wage-related costs, we added to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and physician Part A services (Lines 9, 9.01, 9.02, 10, and 10.01), home office salaries and wage-related costs reported by the hospital on Lines 11, 12, and 12.01, and nonexcluded area wage-related costs (Lines 13, 14, 16, 18, 18.01, and 20).

We note that contract labor and home office salaries for which no corresponding hours are reported were not included. In addition, wage-related costs for specific categories of employees (Lines 16, 18, 18.01, and 20) are excluded if no corresponding salaries are reported for those employees (Lines 2, 4, 4.01, and 6, respectively).

We then calculated a hospital's salaries plus wage-related costs by subtracting from total salaries the salaries plus wage-related costs for teaching physicians, Lines (4.01, 10.01, 12.01, and 18.01), Part A CRNAs (Lines 2 and 16), and residents (Lines 6 and 20).

Step 3—Hours—With the exception of wage-related costs, for which there are no associated hours, we computed total hours using the same methods as described for salaries in Step 2.

Step 4—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocated overhead costs to areas of the hospital excluded from the wage index calculation. First, we determined the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S–3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 3, 5, 7, and Part III, Line 13 of Worksheet S–3). We then computed the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S–3, Part III. Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 3, 5, and 7); (2) we computed overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, 16, 18, 18.01, and 20; and (3) we multiplied the computed overhead wage-related costs by the above excluded area hours ratio. Finally, we subtracted the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3. Using the above method for computing overhead salaries, wage-related costs, and hours to allocate to excluded areas, we also computed these costs excluding all costs associated with GME and CRNAs (Lines 2, 4.01, 6, 10.01, 12.01, and 18.01).

Step 5—For each hospital, we adjusted the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimated the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 1997 through April 15, 1999 for private industry hospital workers from the Bureau of Labor Statistics' *Compensation and Working Conditions.* We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/97	11/15/97	1.03822
11/14/97	12/15/97	1.03561
12/14/97	01/15/98	1.03292
01/14/98	02/15/98	1.03048
02/14/98	03/15/98	1.02828
03/14/98	04/15/98	1.02621
04/14/98	05/15/98	1.02411
05/14/98	06/15/98	1.02200
06/14/98	07/15/98	1.01973
07/14/98	08/15/98	1.01714
08/14/98	09/15/98	1.01424
09/14/98	10/15/98	1.01137
10/14/98	11/15/98	1.00885
11/14/98	12/15/98	1.00669
12/14/98	01/15/99	1.00462
01/14/99	02/15/99	1.00239
02/14/99	03/15/99	1.00000
03/14/99	04/15/99	0.99746

For example, the midpoint of a cost reporting period beginning January 1, 1998 and ending December 31, 1998 is June 30, 1998. An adjustment factor of 1.01973 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 1998 and covered a period of less than 360 days or more than 370 days, we annualized the data to reflect a 1-year cost report. Annualization is accomplished by dividing the data by the number of days in the cost report and then multiplying the results by 365.

Step 6—Each hospital was assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B) or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we added the total adjusted salaries plus wage-related costs obtained in Step 5 (with and without GME and CRNA costs) for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7—We divided the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Because the FY 2002 wage index is based on a blend of average hourly wages, we then added 40 percent of the average hourly wage calculated without removing GME and CRNA costs, and 60 percent of the average hourly wage calculated with these costs excluded.

Step 8—We added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the nation and then divided the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage (using the same blending methodology described in Step 7). Using the data as described above, the national average hourly wage is $22.3096.

Step 9—For each urban or rural labor market area, we calculated the hospital wage index value by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10—Following the process set forth above, we developed a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We added the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divided the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall average hourly wage of $10.7529 for Puerto Rico. For each labor market area in Puerto Rico, we calculated the

Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area may not be less than the area wage index applicable to hospitals located in rural areas in that State. Furthermore, this wage index floor is to be implemented in such a manner as to ensure that aggregate prospective payment system payments are not greater or less than those that would have been made in the year if this section did not apply. For FY 2002, this change affects 217 hospitals in 40 MSAs. The MSAs affected by this provision are identified in Table 4A by a footnote.

F. Revisions to the Wage Index Based on Hospital Redesignation

Under section 1886(d)(8)(B) of the Act, hospitals in certain rural counties adjacent to one or more MSAs are considered to be located in one of the adjacent MSAs if certain standards are met. Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the prospective payment system.

1. Provisions of Public Law 106–554

Section 304 of Public Law 106–554 made changes to several provisions of section 1886(d)(10) of the Act relating to hospital reclassifications and the wage index:

• Section 304(a) amended section 1886(d)(10)(D) of the Act by adding a clause (v) to provide that, beginning with FY 2001, an MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 years, unless the hospital elects to terminate the reclassification. Section 304(a) also provides that the MGCRB must use the 3 most recent years' average hourly wage data in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year (section 1886(d)(10)(D)(vi) of the Act).

• Section 304(b) provides that, by October 1, 2001, the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003. Section 304(b) further requires that if the Secretary applies a statewide wage index to a State, an application under section 1886(d)(10) of the Act by an individual hospital in that State would not be considered.

We address our policy proposals relating to implementation of these three provisions of sections 304(a) and (b) of Public Law 106–554 in section IV.G. of this final rule. The following discussion of the revisions to the wage index based on hospital redesignations reflects those policies.

2. Effects of Reclassification

The methodology for determining the wage index values for redesignated hospitals is applied jointly to the hospitals located in those rural counties that were deemed urban under section 1886(d)(8)(B) of the Act and those hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. Therefore, as provided in section 1886(d)(8)(C) of the Act, the wage index values were determined by considering the following:

• If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.

• If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.

• If including the wage data for the redesignated hospitals increases the wage index value for the area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value.

• The wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

• Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred.

• Rural areas whose wage index values increase as a result of excluding the wage data for the hospitals that have been redesignated to another area have their wage index values calculated exclusive of the wage data of the redesignated hospitals.

• Currently, the wage index value for an urban area is calculated exclusive of the wage data for hospitals that have been reclassified to another area.

For the FY 2002 wage index, we include the wage data for a reclassified urban hospital in both the area to which it is reclassified and the MSA where the hospital is physically located. We believe this improves consistency and predictability in hospital reclassification and wage indexes, as well as alleviates the fluctuations in the wage indexes due to reclassifications. For example, hospitals applying to reclassify into another area will know which hospitals' data will be included in calculating the wage index, because even if some hospitals in the area are reclassified, their data will be included in the calculation of the wage index of the area where they are geographically located. Also, in some cases, excluding the data of hospitals reclassified to another MSA could have a large downward impact on the wage index of the MSA in which the hospital is physically located. The negative impact of removing the data of the reclassified hospitals from the wage index calculation could lead to large wage disparities between the reclassified hospitals and other hospitals in the MSA, as the remaining hospitals would receive reduced payments due to a lower wage index. Our approach is to promote consistency and simplify our rules with respect to how we construct the wage indexes of rural and urban areas. As noted above, in the case of rural hospitals redesignated to another area, the wage index of the rural area where the hospitals are geographically located is calculated by including the wage data of the redesignated hospitals (unless doing so would result in a lower wage index).

Finally, we note that the Medicare Payment Advisory Commission (MedPAC), in its March 2001 ''Report to the Congress: Medicare Payment Policy,'' recommended this policy (p. 82). (Section VII. of this preamble includes a discussion of MedPAC's recommendations and our responses.) To illustrate the potential negative impact on hospitals in an area where reclassifications of some hospitals to another area results in a decline in the wage index after the reclassified hospitals are excluded from the wage

index calculation, MedPAC points out that hospitals in several MSAs have organized to pay qualifying hospitals not to reclassify. Our policy change in this final rule removes this distorted incentive.

Comment: One commenter had some concerns about the reclassification of rural hospitals. This commenter had two points. The first point was that rural hospitals that seek reclassification to urban areas and end up ''empty'' because all the urban hospitals have successfully sought reclassification elsewhere continue to be disadvantaged because the rural hospitals continue to compete with the urban hospitals in that area, but those urban hospitals are receiving even higher payments, while the rural hospitals are not receiving the same payments. The commenter believed that the solution to this dilemma is to allow the rural hospitals that seek reclassification to an ''empty'' MSA to receive the same wage index as the urban hospitals that were able to reclassify out of that MSA, essentially reclassifying both the urban hospitals and the proximate rural hospitals to the same area. One other commenter made this same point about urban hospitals.

The commenter's second point was that, periodically, based on updated census data, new MSAs appear. Sometimes, a rural hospital seeking reclassification to the nearest MSA or rural area is disadvantaged when this occurs because reclassification to the new MSA does not afford the rural hospital the same advantages as reclassification to the MSA to which it formerly sought reclassification, but now is not the closest MSA. The commenter wrote that rural hospitals previously qualified for geographic reclassification to an MSA should retain the option to reclassify to that MSA despite the fact that a closer MSA is created.

Response: First, both rural and, for FY 2002, urban hospitals are advantaged by the fact that we hold all areas harmless when calculating the wage index for hospitals reclassifying into both MSAs and rural areas. While we understand the commenter's point about its competitors, we do not believe that this justifies a ''piggyback'' effect for reclassification purposes wherein either rural or urban hospitals that obtain reclassification into an empty MSA should then be reclassified again to an area to which these hospitals are not proximate. Since a hospital in this type of situation could not obtain reclassification on its own to the area to which the hospitals that have vacated the MSA have reclassified, we do not believe that it would be appropriate to reclassify them based on the reclassification of another hospital.

Second, a hospital that is not subject to the proximity criteria because it has a special status as either a rural referral center or a SCH already has an advantage over other reclassifying hospitals in that it can utilize a larger radius in seeking reclassification opportunities (under § 412.230(a)(3)). Rural referral centers and SCHs may also reclassify to any MSA to which they qualify under § 412.230(b). We believe these criteria provide adequate opportunity for rural referral centers and SCHs to reclassify.

Comment: Commenters generally supported our proposal to include the wage data for a reclassified urban hospital in both the area to which it is reclassified and the MSA where the hospital is physically located. The commenters expressed that this would provide more stability in the calculation of the wage index, allowing them to plan their budgets from year-to-year with more predictability.

We did not receive any negative comments on this proposal; however, we did receive one additional comment that encouraged us to extend the hold harmless provision to a further degree. This commenter believed that both rural and urban hospitals should benefit from the same hold-harmless policy. In other words, an urban hospital's wage data should be included in the area in which it is physically located if it benefits the area. However, The commenter further stated that, on the other hand, if it benefits the area to exclude that hospital's wage data in the event the hospital successfully seeks reclassification for the wage index to another area, then the hospital's data should be excluded. The commenter believed that some urban areas may be harmed by retaining the wage data of urban hospitals that are reclassifying out of those areas.

Response: We appreciate the commenters' support of our proposal to retain an urban hospital's wage data in the area in which it is physically located, even if that hospital successfully seeks reclassification to another area. As we proposed in the proposed rule, in this final rule we are calculating the wage index for urban areas effective for FY 2002 payments by including the wage data for a reclassified urban hospital in both the area to which it is reclassified and the MSA where the hospital is physically located.

In reference to the commenter who believed that we should apply the same hold-harmless policy to urban hospitals as we do to rural hospitals, we note that the rural hold-harmless policy (as described above) is dictated by section 1886(d)(8)(C)(iii) of the Act. We believe that hospitals continue to compete for services with the hospitals that are grouped with them in their respective MSAs. Therefore, it would be appropriate to continue to calculate the wage index for those areas as if those hospitals had not reclassified to another area. As a result, we intend to implement our policy to hold urban areas harmless to the extent that the wages of the hospitals that are physically located within urban areas will continue to be used in the compilation of the wage index whether or not these hospitals successfully seek reclassification elsewhere.

Comment: Several commenters expressed interest in utilizing the occupational mix data to apply for reclassification for the wage index. These commenters pointed out that, at one time, hospitals did have the option to use occupational mix data to seek reclassification for the wage index as those data were made available by the AHA. In addition to the other applicable criteria for reclassification, a hospital that applied for reclassification for the wage index using this criterion was required to show that its average hourly wage, based on occupational mix data, was 90 percent of the area to which it sought reclassification.

Response: Prior to requests for reclassification effective during FY 1999, a hospital could be reclassified for the wage index by showing that its average hourly wage weighted for occupational categories was at least 90 percent of the average hourly wage of the hospitals in the area to which it sought reclassification (in addition to the other applicable criteria for reclassification). Occupational mix data were available from the AHA; however, the AHA stopped collecting the data in 1993. Therefore, because there was no other suitable source of occupational mix data for hospitals to use, we eliminated the option for using this data effective with reclassification requests for FY 1999 (62 FR 45988).

Section 304(c) of Public Law 106–554 requires that the Secretary must provide for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. These data are to be collected by September 30, 2003. Section 304(c) also requires that the data are to be applied in the wage index by October 1, 2004. At that point, the data will be incorporated into a hospital's average

hourly wages. Therefore, the occupational mix data will be reflected in hospital reclassifications for the wage index as it is incorporated into the wage index data. In addition, as soon as viable occupational mix data become available, we will consider providing hospitals with the opportunity to use it to support their reclassification requests.

The wage index values for FY 2002 are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this final rule. Hospitals that are redesignated should use the wage index values shown in Table 4C. Areas in Table 4C may have more than one wage index value because the wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located. When the wage index value of the area to which a hospital is redesignated is lower than the wage index value for the rural areas of the State in which the hospital is located, the redesignated hospital receives the higher wage index value; that is, the wage index value for the rural areas of the State in which it is located, rather than the wage index value otherwise applicable to the redesignated hospitals.

As mentioned earlier, section 304(a) of Public Law 106–554 amended section 1886(d)(10)(D) of the Act by adding a new clause (v) to provide that a reclassification of a hospital by the MGCRB for purposes of the wage index is effective for 3 years (instead of 1 year) unless, under procedures established by the Secretary, the hospital elects to terminate the reclassification before the end of the 3-year period. Section 304(a) of Public Law 106–554 also amended section 1886(d)(10)(D) of the Act to specify that, for applications for reclassification for the wage index for FYs 2003 and later, the MGCRB must base any comparison of the average hourly wage of the hospital with the average hourly wage for hospitals in the area in which it is located and the area to which it seeks reclassification, using data from the most recently published hospital wage survey (as of the date of the hospital's application), as well as data from each of the two immediately preceding surveys. (Our policies in this final rule to incorporate the provisions of section 304(a) of Public Law 106–554 in the regulations are addressed in section IV.G. of this final rule).

Consistent with the section 304(a) amendment, Tables 3A and 3B list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FY 1996, 1997, and 1998 wage data. Table 3A lists these data for urban areas and Table 3B lists these data for rural areas. In addition, Table 2 in the Addendum to this final rule includes the adjusted average hourly wage for each hospital from the FY 1996 and FY 1997 cost reporting periods, as well as the FY 1998 period used to calculate the FY 2002 wage index. Table 2 also shows the 3-year average that the MGCRB will use to evaluate a hospital's application for reclassification for FY 2003 (unless that average hourly wage is later revised in accordance with § 412.63(w)(2)). The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously in this section) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period.

Applications for FY 2003 reclassifications are due to the MGCRB by September 4, 2001. (We note that, as of May 21, 2001, the new location and mailing address of the MGCRB and the Provider Reimbursement Review Board (PRRB) is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670. Also, please specify whether the mail is intended for the MGCRB or the PRRB.)

We indicated in the proposed rule that, at the time the proposed wage index was constructed, the MGCRB had completed its review of FY 2002 reclassification requests. The final FY 2002 wage index values incorporate all 643 hospitals redesignated for purposes of the wage index (hospitals redesignated under section 1886(d)(8)(B) or section 1886(d)(10) of the Act for FY 2002. Since publication of the May 4 proposed rule, the number of reclassifications has changed because some MGCRB decisions were still under review by the Administrator and because some hospitals decided to withdraw their requests for reclassification.

Changes to the wage index that resulted from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process have been incorporated into the wage index values published in this final rule. The changes may affect not only the wage index value for specific geographic areas, but also the wage index value redesignated hospitals receive; that is, whether they receive the wage index value for the area to which they are redesignated, or a wage index value that includes the data for both the hospitals already in the area and the redesignated hospitals. Further, the wage index value for the area from which the hospitals are redesignated may be affected.

Under § 412.273, hospitals that have been reclassified by the MGCRB were permitted to withdraw their applications within 45 days of the publication of the May 4, 2001 proposed rule. The request for withdrawal of an application for reclassification that would be effective in FY 2002 had to be received by the MGCRB by June 18, 2001. A hospital that requested to withdraw its application may not later request that the MGCRB decision be reinstated.

In addition, because the 3-year effect of the amendment made by section 304(a) of Public Law 106–554 is applicable to reclassifications for FY 2001 (which had already taken place prior to the date of enactment of Public Law 106–554) and because the application process for reclassification for FY 2002 had already been completed by the date of enactment, we are deeming hospitals that are reclassified for purposes of the wage index to one area for FY 2001 and are reclassified for purposes of the wage index or the standardized amount to another area for FY 2002 to be reclassified to the area for which they applied for FY 2002, unless they elected to receive the wage index reclassification they were granted for FY 2001. Consistent with our application withdrawal procedures under § 412.273, we allowed hospitals that wished to receive, for FY 2002, the reclassification they were granted for FY 2001, to withdraw their applications by June 18, 2001 also.

Comment: Two commenters requested us to continue publishing the case-mix index because it assists hospitals in monitoring possible referral center qualifying status and in preparing applications for reclassification to use another area's standardized amount. (We also received numerous telephone calls with this request.)

Response: Prior to this year, the case-mix index was published in Table 3C. This index shows the average DRG relative weight for discharges from a prior fiscal year. Due to the requirement to publish so much additional average hourly wage data in Tables 2, 3A, and 3B, we stopped publishing the case-mix index beginning with the May 4, 2001 proposed rule.

In light of public comments and in balancing the requirements for additional publication of average hourly wage data, we will resume publishing the case-mix index, but not in the **Federal Register**. Beginning with the publication date of this final rule, we will make the case-mix index for FY 2000 and future fiscal years available on

the internet at: http://www.hcfa.gov/medicare/ippsmain.htm. We intend to update the case-mix index at this website to coincide with the publication of the annual proposed and final rules.

3. Statewide Wage Index

As stated earlier, section 304(b) of Public Law 106–554 requires the Secretary to establish, by October 1, 2001, a process (based on the voluntary process utilized by the Secretary under section 1848 of the Act) under which an appropriate statewide entity may apply to have all the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, beginning in FY 2003. Section 304(b) further requires that, if the Secretary applies a statewide wage index to an area, an application by an individual hospital in that area would not be considered. We believe the reference to the voluntary process utilized by the Secretary under section 1848 of the Act refers to the process whereby we allow a State containing multiple physician fee schedule payment areas (and thus multiple geographic adjustment factors) to voluntarily convert to a single statewide payment area with a single geographic adjustment factor (see § 414.4(b), as discussed in the June 24, 1994 **Federal Register** (59 FR 32759).

Section IV.G. of this final rule contains our policy for implementing the provisions of section 304(b) in regulations. We are providing that hospitals that seek a statewide geographic reclassification under the amendments made by section 304(b) of Public Law 106–554 must apply to the MGCRB with the same deadlines as other hospitals. An approved application by the MGCRB will mean that the data of all the hospitals in the State will be used in computing and applying the wage index for that State. We are providing that the statewide wage index is applicable for 3 years from the date of approval or until all of the participating hospitals terminate their approved statewide wage index reclassification (effective with the next full fiscal year after their termination request), whichever occurs first.

4. Section 402 of Public Law 106–113

Beginning October 1, 1988, section 1886(d)(8)(B) of the Act required us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area under the standards published in the **Federal Register** on January 3, 1980 (45 FR 956) for designating MSAs (and for designating NECMAs), and if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of *all* contiguous MSAs (or NECMAs)). Hospitals that met the criteria using the January 3, 1980 version of these OMB standards were deemed urban for purposes of the standardized amounts and for purposes of assigning the wage index.

During FY 1994, we incorporated the revised MSA definitions based on 1990 census population data. As a result, some counties that previously were treated as an adjacent county under section 1886(d)(8)(B) of the Act officially became part of certain MSAs. However, as specified in the Act, we continued to utilize the January 3, 1980 standards. For FY 2000, there were 27 hospitals in 22 counties affected by this provision.

On March 30, 1990, OMB issued revised 1990 standards (55 FR 12154). There has been an increasing amount of interest by the hospital industry in using the 1990 standards as opposed to the 1980 standards to determine which hospitals qualify under the provisions set forth in section 1886(d)(8)(B) of the Act. Section 402 of Public Law 106–113 provides that, with respect to FYs 2001 and 2002, a hospital may elect to have the 1990 standards applied to it for purposes of section 1886(d)(8)(B) and that, beginning with FY 2003, hospitals will be required to use the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census.

We worked with staff of the Population Distribution Branch within the Population Division of the Census Bureau to compile a list of hospitals that meet the March 30, 1990 standards using 1990 census population data and information prepared for the Metropolitan Area Standards Review Project. The conditions that must be met for a hospital located in a rural county adjacent to one or more urban areas to be treated as being located in the urban area to which the greatest number of workers in the rural county commute are as follows:

- The rural county would otherwise be considered part of an MSA but for the fact that the rural county does not meet the standard established by OMB relating to the commuting rate of workers between the county and the central county or counties of any adjacent MSA.
- The county would meet the commuting standard if commuting to (and where applicable, from) the central county or central counties of all adjacent MSAs or NECMAs (rather than to just one) were considered.

A county meeting the above commuting standards must also meet the other standards established by OMB for inclusion in an MSA as an outlying county. In order to meet these requirements, the rural county must have a degree of ''metropolitan character.'' ''Metropolitan character'' is established by meeting one of the following OMB standards, which were published in the **Federal Register** on March 30, 1990:

a. At least 50 percent of the employed workers residing in the county commute to the central county/counties, and either—

- The population density of the county is at least 25 persons per square mile; or
- At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).

b. From 40 to 50 percent of the employed workers commute to the central county/counties, and either—

- The population density is at least 35 persons per square mile; or
- At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).

c. From 25 to 40 percent of the employed workers commute to the central county/counties and either the population density of the county is at least 50 persons per square mile, or any two of the following conditions exist:

- Population density is at least 35 persons per square mile.
- At least 35 percent of the population is urban.
- At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanizer area(s).

d. From 15 to 25 percent of the employed workers commute to the central county/counties, the population density of the county is at least 50 persons per square mile, and any two of the following conditions also exist:

- Population density is at least 60 persons per square mile.
- At least 35 percent of the population is urban.
- Population growth between the last two decennial censuses is at least 20 percent.
- At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).

Also accepted as meeting this commuting requirement under item d. are:

• The number of persons working in the county who live in the central county/counties is equal to at least 15 percent of the number of employed workers living in the county; or

• The sum of the number of workers commuting to and from the central county/counties is equal to at least 20 percent of the number of employed workers living in the county.

e. From 15 to 25 percent of the employed workers commute to the central county/counties, the population density of the county is less than 50 persons per square mile, and any two of the following conditions also exist:

• At least 35 percent of the population is urban.

• Population growth between the last two decennial censuses is at least 20 percent.

• At least 10 percent of the population, or at least 5,000 persons, lives in the qualifier urbanized area(s).

f. At least 2,500 of the population lives in a central city of the MSA located in the qualifier urbanized area(s).

When we apply the 1990 standards as opposed to 1980 standards, the number of qualifying counties increases from 22 to 31. On the basis of the evaluation of these data, effective for discharges occurring on or after October 1, 2001, hospitals listed in the first column of the following table are considered, for purposes of assigning the inpatient standardized amount and the wage index, to be located in the corresponding urban area in the second column:

Rural county	MSA
Chilton, AL	Birmingham, AL
Marshall, AL	Huntsville, AL
Talladega, AL	Anniston, AL
Bradford, FL	Jacksonville, FL
Hendry, FL	West Palm Beach-Boca Raton, FL
Putnam, FL	Gainesville, FL
Jackson, GA	Athens, GA
Christian, IL	Springfield, IL
Macoupin, IL	St. Louis, MO–IL
Piatt, IL	Champaign-Urbana, IL
Brown, IN	Indianapolis, IN
Carroll, IN	Lafayette, IN
Henry, IN	Indianapolis, IN
Jefferson, KS	Topeka, KS
Barry, MI	Kalamazoo-Battle Creek, MI
Cass, MI	Benton Harbor, MI
Ionia, MI	Grand Rapids-Muskegon-Holland, MI
Shiawassee, MI	Flint, MI
Tuscola, MI	Saginaw-Bay City-Midland, MI
Caswell, NC	Greensboro-Winston Salem-High Point, NC
Greene, NC	Greenville, NC
Harnett, NC	Raleigh-Durham-Chapel Hill, NC
Wilson, NC	Rocky Mount, NC
Preble, OH	Dayton-Springfield, OH
Van Wert, OH	Lima, OH
Adams, PA	York, PA
Lawrence, PA	Pittsburgh, PA
Monroe, PA	Newark, NJ
Schuylkill, PA	Reading, PA
Jefferson, WI	Milwaukee-Waukesha, WI
Walworth, WI	Milwaukee-Waukesha, WI

There are 14 counties that meet the qualifying criteria using 1990 standards that did not meet the criteria using the 1980 standards. These 14 counties are:

Chilton, AL
Talladega, AL
Bradford, FL
Hendry, FL
Putnam, FL
Jackson, GA
Piatt, IL
Brown, IN
Carroll, IN
Greene, NC
Wilson, NC
Adams, PA
Monroe, PA
Schuylkill, PA.

In addition, when we apply the 1980 standards for three of the counties, the MSA assigned is different from the MSA that would be assigned using the 1990 standards. These counties are as follows:

Rural county	1980 MSA designation	1990 MSA designation
Ionia, MI	Lansing-East Lansing, MI	Grand Rapids-Muskegon-Holland, MI.
Caswell, NC	Danville, VA	Greensboro-Winston Salem-High Point, NC.
Harnett, NC	Fayetteville, NC	Raleigh-Durham-Chapel Hill, NC.

Section 402 of Public Law 106–113 states that hospitals may elect to use either the January 3, 1980 standards or the March 30, 1990 standards for payments during FY 2001 and FY 2002. We are assuming hospitals will elect to go to the MSA resulting in the highest payment amount accounting for the applicable wage indexes and standardized amounts. Based on our analysis, we believe all hospitals in the designated rural counties would benefit by being included in the respective MSAs shown above. Therefore, we proposed to assign the FY 2002

standardized amount and wage index of each respective MSA to the affected hospitals. Hospitals electing not to use the 1990 standards would be required to notify their fiscal intermediary in writing of such election prior to September 1, 2001, in order to allow sufficient time to reflect this change in our payment systems.

We note that five rural counties no longer meet the qualifying criteria when we apply the revised OMB standards. These rural counties are as follows: Indian River, FL; Mason, IL; Owen, IN; Morrow, OH; and Lincoln, WV. For FY 2002, we continue to treat these hospitals as attached to an MSA on the basis of the 1980 standards. Beginning FY 2003, they must meet the 1990 standards to continue to be treated as such.

We stated in the August 1, 2000 final rule that implemented changes to the prospective payment system for FY 2001 that we were in the process of working with OMB to identify the hospitals that would be affected by section 402 of Public Law 106–113 (65 FR 47076). We further indicated we would revise payments to hospitals in the affected counties as soon as data were available. Now that the affected counties have been identified, hospitals in the 14 counties identified above will be offered the opportunity to elect this designation, as previously described. We will provide further information related to this election, including recalculated wage indexes, through a forthcoming program memorandum.

Finally, three hospitals located in counties affected by the revised OMB standards also have been reclassified by the MGCRB. The affected hospitals are listed below. If the hospitals did not wish to be reclassified for FY 2002 based on their new designation as described above, they had to follow the procedures described above for requesting that their application for reclassification be withdrawn.

Provider No.	1990 MSA Designation	FY 2002 reclassification, MSA
34–0071	Raleigh-Durham-Chapel Hill, NC	Fayetteville, NC.
34–0124	Raleigh-Durham-Chapel Hill, NC	Fayetteville, NC.
34–0126	Rocky Mount, NC	Raleigh-Durham-Chapel Hill, NC (wage index only).

5. Provisions of the August 1, 2000 Interim Final Rule: Sections 152(a), 153, and 154a) of Public Law 106–113

In the August 1, 2000 interim final rule with comment period, we implemented sections 152(a), 153, and 154(a) of Public Law 106–113. These sections contained provisions under which hospitals in certain counties are deemed to be located in specified areas for purposes of payment under the hospital inpatient prospective payment system, for discharges occurring during FY 2000. For payment purposes, hospitals under section 152(a) are to be treated as though they were reclassified for purposes of both the standardized amount and the wage index. Sections 153 and 154(a) did not affect the standardized amount. In the interim final rule, we calculated FY 2000 wage indexes for hospitals in the affected counties. These wage indexes are listed below. No other hospitals' FY 2000 wage indexes were affected, including those hospitals in the areas to which these affected hospitals were reclassified, as well as nonreclassified hospitals located in the areas from which these hospitals were reclassified.

We also implemented section 152(a), which provided that, for purposes of making payments under section 1886(d) of the Act for FY 2000—

- To hospitals in Iredell County, North Carolina, Iredell County was deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina MSA;
- To hospitals in Orange County, New York, Orange County was deemed to be located in the New York, New York MSA;
- To hospitals in Lake County, Indiana and Lee County, Illinois, Lake County and Lee County were deemed to be located in the Chicago, Illinois MSA;
- To hospitals in Hamilton-Middletown, Ohio, Hamilton-Middletown was deemed to be located in the Cincinnati, Ohio-Kentucky-Indiana MSA;
- To hospitals in Brazoria County, Texas, Brazoria County was deemed to be located in the Houston, Texas MSA;
- To hospitals in Chittenden County, Vermont, Chittenden County was deemed to be located in the Boston-Worcester-Lawrence-Lowell-Brockton, Massachusetts-New Hampshire MSA.

In accordance with section 153 of Public Law 106–113, for discharges occurring during FY 2000, the Hattiesburg, Mississippi MSA wage index was recalculated by including the wage data for Wesley Medical Center. In accordance with section 154(a), the Allentown-Bethlehem-Easton, Pennsylvania MSA FY 2000 wage index was recalculated by including the wage data for Lehigh Valley Hospital.

The following table shows the changes to the FY 2000 wage index values for the hospitals in the affected counties. Hospitals affected by section 152(a) of Public Law 106–113 were also considered reclassified for purposes of the standardized amount.

County or MSA	New MSA (for wage index and standardized amount)	New wage index	New Georgraphic Adjustment Factor (GAF)
Iredell County, NC	1520	0.9434	0.9609
Orange County, NY	5600	1.4342	1.2801
Lake County, IN	1600	1.0750	1.0508
Lee County, IL	1600	1.0750	1.0508
Hamilton-Middletown, OH	1640	0.9419	0.9598
Brazoria County, TX	3360	0.9388	0.9577
Chittenden County, VT	1123	1.1359	1.0912
Hattiesburg, MS MSA	3285	0.7634	0.8312
Allentown-Bethlehem-Easton, PA MSA	0240	1.0228	1.0156

G. Requests for Wage Data Corrections

In the May 4, 2000 proposed rule, we stated that, to allow hospitals time to construct the proposed FY 2002 hospital wage index, we would make available in May 2001 a final public data file containing the FY 1998 hospital wage data.

The final wage data file was released on May 4, 2001. As noted above in section III.D. of this preamble, this file included hospitals' cost report data obtained from Worksheet S–3, Parts II and III of their FY 1998 Medicare cost reports. In addition, Table 2 in the Addendum to this final rule contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 1998 data used to construct the final FY 2002 wage index.

Under revised procedures, hospitals were given an opportunity to correct any incorrectly reported FY 1998 wage data on their cost reports and submit complete detailed supporting documentation to their intermediaries by March 9, 2001. Wage data corrections had to be reviewed and verified by the intermediary and transmitted to HCFA on or before April 9, 2001. These deadlines were necessary to allow sufficient time to review and process the data so that the final wage index calculation could be completed for development of the final prospective payment rates in this final rule.

We created the process described above to resolve all substantive wage data correction disputes before we finalize the wage data for the FY 2002 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above were not afforded a later opportunity to submit wage data corrections or to dispute the intermediary's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to later challenge, before the Provider Reimbursement Review Board, HCFA's failure to make a requested data revision (See *W. A. Foote Memorial Hospital v. Shalala,* No. 99–CV–75202–DT (E.D. Mich. 2001)).

As stated above, the final wage data public use file was released on May 4, 2001. Hospitals had an opportunity to examine both Table 2 of the proposed rule and the May 4 final public use wage data file (which reflected revisions to the data used to calculate the values in Table 2) to verify the data HCFA was using to calculate the wage index. Hospitals had until June 4, 2001, to submit requests to correct errors in the final wage data due to data entry or tabulation errors by the intermediary or HCFA. The correction requests considered at that time were limited to errors in the entry or tabulation of the final wage data that the hospital could not have known about before the release of the final wage data public use file.

If, after reviewing the May 2001 final data file, a hospital believed that its wage data are incorrect due to a fiscal intermediary or HCFA error in the entry or tabulation of the final wage data, it was provided an opportunity to send a letter to both its fiscal intermediary and HCFA, outlining why the hospital believed an error exists and provide all supporting information, including dates. These requests had to be received by us and the intermediaries no later than June 4, 2001.

Changes to the hospital wage data were made in those very limited situations involving an error by the intermediary or HCFA that the hospital could not have known about before its review of the final wage data file. Specifically, neither the intermediary nor HCFA accepted the following types of requests at that stage of the process:

- Requests for wage data corrections that were submitted too late to be included in the data transmitted to HCFA on or before April 9, 2001.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 2001 wage data file.
- Requests to revisit factual determinations or policy interpretations made by the intermediary or HCFA during the wage data correction process.

Verified corrections to the wage index received timely (that is, by June 4, 2001) are incorporated into the final wage index in this final rule, to be effective October 1, 2001.

Again, we believe the wage data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage data to the intermediary's attention. Moreover, because hospitals had access to the final wage data by early May 2001, they had the opportunity to detect any data entry or tabulation errors made by the intermediary or HCFA before the development and publication of the FY 2002 wage index and its implementation on October 1, 2001. If hospitals availed themselves of this opportunity, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified after that date, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.63(w)(2), we may make midyear corrections to the wage index only in those limited circumstances in which a hospital can show (1) that the intermediary or HCFA made an error in tabulating its data; and (2) that the hospital could not have known about the error, or did not have an opportunity to correct the error, before the beginning of FY 2002 (that is, by the June 4, 2001 deadline). As indicated earlier, since a hospital had the opportunity to verify its data, and the intermediary notified the hospital of any changes, we do not foresee any specific circumstances under which midyear corrections would be necessary. However, should a midyear correction be necessary, the wage index-change for the affected area will be effective prospectively from the date the correction is made.

H. Modification of the Process and Timetable for Updating the Wage Index

Although the wage data correction process described above has proven successful in the past for ensuring that the wage data used each year to calculate the wage indexes are generally reliable and accurate, we are concerned about the growing volume of wage data revisions initiated by hospitals during February and the first week of March. We first discussed this issue in the FY 1998 proposed rule (62 FR 29918). At that time, we noted that, in developing the FY 1997 wage index, the wage data were revised between the proposed and final rules for more than 13 percent of the hospitals (approximately 700 of 5,200). Last year, in developing the FY 2001 wage index, the wage data were revised between the proposed and final rules for more than 32 percent of the hospitals (1,605 of 4,950). This year, in developing the FY 2002 wage index, the wage data were revised between the proposed rule and the final rule for 30 percent of the hospitals (1,473 of 4,910).

In the May 4, 2001 proposed rule, we indicated that since hospitals are expected to submit complete and accurate cost report data, and intermediaries review and request hospitals to correct problematic wage data before the data are submitted to HCFA in mid-November, we believed there should be limited revisions at this stage of the process. We reminded the hospital community that the primary purpose of this file is to allow hospitals to verify that we have their correct data on file. However, according to information received from the intermediaries, these late revisions are frequently due to hospitals' lack of responsiveness in providing sufficient information to the intermediaries during the desk reviews (that is, during the

intermediary's review of the hospital's cost report).

In the proposed rule, we proposed two changes to the wage index development process and timetable beginning with the FY 2003 wage index. We believed these changes would encourage earlier submissions of wage data revisions by hospitals and would allow intermediaries more time to address the heavy volume of revisions requested after the intermediaries have completed their desk reviews of these data. First, we proposed to release the preliminary wage data file by early January rather than early February. As with the current preliminary file, the January file would include desk reviewed wage data that intermediaries submitted to us by November of the previous year and any timely revisions we received from intermediaries prior to release of the January file. Hospitals would be allowed until early February to submit requests for wage data revisions to their intermediaries. Second, intermediaries would be allowed approximately 8 weeks from the hospitals' deadline for submitting revision requests (that is, until early March) to review and transmit revised wage data to us.

We believed that the proposed revised schedule would improve the quality of the wage index by allowing intermediaries more time to sufficiently review wage data revisions before the data are submitted to us. Further, we believed the proposed revised process would encourage hospitals to submit revisions earlier, so the proposed wage index, from which hospitals base geographic reclassification decisions, is more accurate.

The timetable for developing the annual update to the wage index is as follows (an asterisk indicates no change from prior years):

Mid-November *

All desk reviews for hospitals wage data are completed and revised data transmitted by the fiscal intermediaries to HCRIS.

Early December *

CMS compiles file of wage data, received by mid-November, and sends it to the fiscal intermediaries for verification.

Early January

Edited wage data are available for release to the public.

Early February

Deadline for hospitals to request wage data revisions and provide adequate documentation to support the request.

April/May *

Proposed rule published with 60-day comment period and 45-day withdrawal deadline for hospitals applying for geographic reclassification.

Early April *

Deadline for the fiscal intermediaries to submit all revisions resulting from the hospitals' requests for adjustments (as of early February) (and verification of data submitted as of early January).

Deadline for hospital's to request CMS's intervention in cases where the hospital disagrees with the fiscal intermediary's policy interpretations pertaining to the allowability of particular costs.

Late April *

Fiscal intermediaries will alert hospitals to the availability of the final wage data file for their review and inform hospitals of the June deadline for hospitals to submit correction requests for corrections to errors due to CMS or fiscal intermediary mishandling of the final wage data.

Early May *

Release of final wage data public use file on CMS web page and through public use files office.

Early June *

Deadline for hospitals to submit correction requests to both CMS and the fiscal intermediaries to correct errors due to CMS or fiscal intermediary mishandling of the final wage data.

August 1 *

Publication of the final rule.

October 1 *

Effective date of updated wage index.

Comment: One commenter agreed, in general, with the premise of the proposed revised schedule. The commenter recommended that we publish the preliminary wage data file in August, using data from the hospitals' as-filed cost reports before fiscal intermediaries begin the wage index desk reviews. Hospitals would then have until October 1 to submit requests, along with supporting documentation, to correct errors. The commenter's proposal would give fiscal intermediaries until November 30 to complete the desk review and transmit the wage index data to us. The commenter believed that implementation of the recommended schedule eliminates the fiscal intermediary's duplication of effort (that is, reviewing the data a second time when hospitals request changes after the desk review, and then resubmitting the data to us) that exists in the current process.

Response: We appreciate the commenter's general support for our proposal to revise the wage index schedule, and we will give the commenter's recommended process careful consideration in developing future updates to the wage index. Having received no other comments opposing our proposed schedule, we will implement that schedule, beginning with the FY 2003 wage index. We believe that our revised schedule is a logical step in the evolution of the wage index development process. We will monitor the effectiveness of the revised schedule.

IV. Other Decisions and Changes to the Prospective Payment System for Inpatient Operating Costs and Graduate Medical Education Costs

A. Sole Community Hospitals (SCHs) (§§ 412.63, 412.71, 412.72, 412.73, 412.75, 412.77, and 412.92)

For the benefit of the reader, in this final rule, we are discussing and clarifying many of the rules and policies governing SCHs because of the legislative changes that have occurred in recent years. It has been several years since the SCH criteria have been published in one location. Rather than continue to refer to various **Federal Register** documents and sections of the Code of Federal Regulations, we are publishing a detailed discussion of these policies, making further changes to incorporate the provisions of sections 213, 302, 303, 304, and 311 of Public Law 106–554, and clarifying other related policies.

Under the hospital inpatient prospective payment system, special payment protections are provided to an SCH. Section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that, by reason of factors such as isolated location, weather conditions, travel conditions, absence of other like hospitals (as determined by the Secretary), or historical designation by the Secretary as an Essential Access Community Hospital (EACH), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations that set forth the criteria that a hospital must meet to be classified as an SCH are at § 412.92. To be classified as an SCH, a hospital must either have been designated as an SCH prior to the beginning of the prospective payment system on October 1, 1983, and must be located more than 35 miles from other like hospitals, or the hospital must be

located in a rural area and meet one of the following requirements:

• It is located more than 35 miles from other like hospitals.

• It is located between 25 and 35 miles from other like hospitals, and it—

—Serves at least 75 percent of all inpatients, or 75 percent of Medicare beneficiary inpatients, within a 35-mile radius or, if larger, within its service area; or

—Has fewer than 50 beds and would qualify on the basis of serving 75 percent of its area s inpatients except that some patients seek specialized care unavailable at the hospital.

• It is located between 15 and 25 miles from other like hospitals, and because of local topography or extreme weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.

• The travel time between the hospital and the nearest like hospital is at least 45 minutes because of distance, posted speed limits, and predictable weather conditions.

Effective with hospital cost reporting periods beginning on or after April 1, 1990, section 1886(d)(5)(D)(i) of the Act, as amended by section 6003(e) of Public Law 101–239, provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

• The Federal rate applicable to the hospital.

• The updated hospital-specific rate based on FY 1982 costs per discharge.

• The updated hospital-specific rate based on FY 1987 costs per discharge.

Effective with hospital cost reporting periods beginning on or after October 1, 2000, section 1886(b)(3)(I)(i) of the Act, as added by section 405 of Public Law 106–113 and amended by section 213 of Public Law 106–554, provides for other options, in addition to the three bulleted options in the above paragraph, for determining which rate would yield the greatest aggregate payment. For discharges for FY 2001 through FY 2003, these additional optional rates are—

• A phase-in blended rate of the updated hospital-specific rate based on FY 1982 costs per discharge and an FY 1996 hospital-specific rate; or

• A phase-in blended rate of the updated hospital-specific rate based on FY 1987 costs per discharge and an FY 1996 hospital-specific rate.

For discharges beginning in FY 2004, the additional optional rate would be 100 percent of the FY 1996 hospital-specific rate.

For each cost reporting period, the fiscal intermediary determines which of the payment options will yield the highest rate of payment. Payments are automatically made at the highest rate using the best data available at the time the fiscal intermediary makes the determination. However, it may not be possible for the fiscal intermediary to determine in advance precisely which of the rates will yield the highest payment by year's end. In many instances, it is not possible to forecast the outlier payments, the amount of the DSH adjustment, or the IME adjustment, all of which are applicable only to payments based on the Federal rate. The fiscal intermediary makes a final adjustment at the close of the cost reporting period to determine precisely which of the payment rates would yield the highest payment to the hospital.

If a hospital disagrees with the fiscal intermediary's determination regarding the final amount of program payment to which it is entitled, it has the right to appeal the fiscal intermediary's decision in accordance with the procedures set forth in Subpart R of Part 405, which concern provider payment determinations and appeals.

In calculating a hospital-specific rate for an SCH based on its FY 1996 cost reporting period, we will, to the extent possible, use the same methodology that we used to calculate the hospital-specific rate based on either the FY 1982 or FY 1987 cost reporting period. That methodology is set forth in §§ 412.71, 412.72, 412.73, 412.75 and 412.77.

• If a hospital has a cost reporting period ending in FY 1982, it will be paid a hospital-specific rate based on its FY 1982 costs; or a hospital-specific rate based on its FY 1987 costs; or a hospital-specific rate based on its FY 1996 costs (which, until FY 2004, would be a blend of the greater of the FY 1982 or FY 1987 costs and the FY 1996 costs); or it will be paid based on the Federal rate.

• If a hospital has no cost reporting period ending in FY 1982, it will be paid a hospital-specific rate based on its FY 1987 costs; or a hospital-specific rate based on its FY 1996 costs (which, until FY 2004, would be a blend of its FY 1987 costs and FY 1996 costs); or it will be paid based on the Federal rate.

• If a hospital has no cost reporting period ending in either FY 1982 or FY 1987, it will be paid based on its FY 1996 costs; or it will be paid based on the Federal rate.

• If a hospital has no cost reporting period ending in FY 1982, FY 1987, or FY 1996, it cannot be paid based on a hospital-specific rate; it will be paid based on the Federal rate.

• If a hospital was operating during any or all of FY 1982, FY 1987, or FY 1996, but, for some reason, the cost report records are no longer available, the hospital will be treated as if it had no cost report for the applicable period. Section 1886(b)(3)(C) of the Act specifies the available periods that may be used.

For each SCH, the fiscal intermediary will calculate a hospital-specific rate based on the hospital's FY 1982, FY 1987, or FY 1996 cost report as follows:

• Determine the hospital's total allowable Medicare inpatient operating cost, as stated on the cost report.

• Divide the total Medicare operating cost by the number of Medicare discharges (without adjusting for transfers) in the cost reporting period to determine the base period cost per case.

• In order to take into consideration the hospital's individual case-mix, the base year cost per case is divided by the hospital's case-mix index applicable to the cost reporting period. This step is necessary to adjust the hospital's base period cost for case mix. This is done to remove the effects of case mix from the base period costs per case. Payments using these base period costs are then adjusted to reflect the actual case mix during the payment year. A hospital's case mix is computed based on its Medicare patient discharges subject to DRG-based payment.

The fiscal intermediary will inform each SCH of its hospital-specific rate based on its applicable cost reporting period within 180 days after the start of its cost reporting period.

(The provisions of section 213 of Public Law 106–554 relating to the extension to all SCHs the option to rebase using their FY 1996 operating costs, for cost reporting periods beginning on or after October 1, 2000, were addressed in the June 13, 2001 interim final rule with comment period, and are finalized in this final rule.)

An SCH is also eligible for a payment adjustment if, for reasons beyond its control, it experiences a decline in volume of greater than 5 percent compared to its preceding cost reporting period. This adjustment is also available to hospitals that could qualify as SCHs but choose not to be paid as SCHs; that is, hospitals that qualify and successfully apply to be designated as SCHs but continue to receive payments based on the Federal rate. In addition, section 6003(c)(1) of Public Law 101–239 deleted the sunset date on the 5-percent volume decline adjustment, thus allowing SCHs to receive the adjustment indefinitely. The sunset provision was included under section 1886(d)(5)(C)(ii) of the Act. (Section 6003(c)(1) of Public Law 101–239 amended that provision and

redesignated it as section 1886(d)(5)(D) of the Act.)

In the September 1, 1983, issue of the **Federal Register** (48 FR 39781), we stated that any hospital designated as an SCH would retain that status until it experienced a change in circumstances. Section 6003(e)(3) of Public Law 101–239 specifically stated that any hospital classified as an SCH as of the date of enactment of Public Law 101–239 (December 19, 1989), will retain its SCH status even if the hospital did not meet the criteria established under section 6003(e)(1) of that law. These hospitals are the ''grandfathered'' SCH hospitals. Therefore, we have continued to allow hospitals designated as SCHs prior to December 19, 1989, to be ''grandfathered'' under current criteria.

In the June 4, 1991 **Federal Register**, we stated that a hospital's special status as an SCH would not be retained in light of the hospital's geographic reclassification for purposes of the standardized amount. In the event the hospital's reclassification ceases, it must reapply for special status and must meet all of the applicable qualifying criteria in effect at the time it seeks requalification (56 FR 25482). However, in the event a ''grandfathered'' SCH was successfully reclassified, it would be reinstated as an SCH if its reclassification ceased.

Section 401(a) of Public Law 106–113 established that any subsection (d) hospital (section 1886(d) of the Act) located in an urban area may be redesignated as being located in a rural area if the hospital meets one of several criteria established by the legislation. One of these criteria is that the hospital could qualify as an SCH if the hospital were located in a rural area. Under this provision, an urban hospital that may have been ''grandfathered'' as an SCH could now qualify and receive payment as an SCH if it met the criteria of a rural SCH instead of as an urban SCH. Given this extension of SCH eligibility, we no longer believe it is necessary to extend special protection to ''grandfathered'' SCHs that successfully apply for geographic reclassification through the MGCRB for the standardized amount after their MGCRB reclassification ends. Therefore, a hospital that loses its SCH status through a change in circumstances, such as reclassification through the MGCRB for the standardized amount, will not be reinstated as a SCH unless it can meet all of the SCH qualifying criteria in effect at the time it seeks requalification. This circumstance falls under the provisions of §§ 412.92 (b)(3) and (b)(5), which state that an approved classification as an SCH remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. We believe that a successful reclassification by the MGCRB fits the definition of a change in circumstances.

Because some hospitals may not have understood the effect reclassification would have on their special status, in the May 4 proposed rule we permitted affected hospitals, under existing § 412.273(a), the option to withdraw their applications for reclassification for FY 2002, even if the MGCRB had issued a decision, by submitting a withdrawal request to the MGCRB within 45 days of publication of this proposed rule. Finally, just as a competing hospital that closes leaves an opportunity for an existing hospital to qualify as an SCH, a new hospital that opens in an area with an existing hospital designated as an SCH endangers the SCH status of the existing hospital.

As of October 1, 1997, no designations of hospitals as EACHs can be made. The EACHs designated by CMS before October 1, 1997, will continue to be paid as SCHs for as long as they comply with the terms, conditions, and limitations under which they were designated as EACHs.

Under § 412.92(b)(2), we define the effective dates for several situations in which a hospital gains or gives up SCH status. First, SCH status and the associated payment adjustment is effective 30 days after CMS's written notification to the SCH. Thus, 30 days after the issuance of CMS's notice of approval, the hospital is considered to be an SCH and the payment adjustment is applied to discharges occurring on or after that date.

Second, § 412.92(b)(4)(ii) defines the effective date when a hospital chooses to give up its SCH status. Our policy has always been that an SCH can elect to give up its SCH status at any time by submitting a written request to the appropriate CMS regional office through its fiscal intermediary. The change to fully national rates becomes effective no later than 30 days after the hospital submits its request. We believe that the ''no later than 30 days'' policy for the effective date for cancelling SCH status is in keeping with the prospective nature of the prospective payment system. In addition, the 30-day timeframe to give up SCH status provides the fiscal intermediaries with enough time to alter their automated payment systems prospectively, thus avoiding expensive and time-consuming reprocessing of claims. The variable timeframe of ''no later than 30 days from the date of the hospital's request'' also permits the regional office, the fiscal intermediary, and the hospital to select a mutually agreeable date, for example, at the end of a month, to facilitate the change in SCH status. We expect that hospitals will anticipate when they wish to give up SCH status and to submit their requests in sufficient time to permit the 30-day period for making the change.

In addition, § 412.92(b)(2)(ii) defines the effective date of SCH status in the situation where a final and nonappealable administrative or judicial decision reverses CMS's denial of SCH status to a hospital. In this situation, if the hospital's application was submitted on or after October 1, 1983, the effective date will be 30 days after the date of CMS's original written notification of denial.

Under § 412.92(b)(2)(iii), we define retroactive approval of SCH status. If a hospital is granted retroactive approval of SCH status by a final and nonappealable court order or an administrative decision under subpart R of part 405 of the regulations, and it wishes its SCH status terminated prior to the current date (that is, it wishes to be paid as an SCH for a time-limited period, all of which is in the past), it must submit written notice to the CMS regional office through its fiscal intermediary within 90 days of the court order or the administrative decision. This written notice must clearly state that, although SCH status was granted retroactively by the court order or by the administrative decision, the hospital wants this status terminated as of a specific date. If written notice is not received within 90 days of the court order or the administrative decision, SCH status will continue. Written requests to terminate SCH status that are received subsequent to the 90-day period will be effective no later than 30 days after the request is submitted, as discussed above.

Under § 412.92(c)(1), we define mileage. We believe that mileage should continue to be measured by the shortest route over improved roads maintained by any local, State, or Federal government entity for public use. We consider improved roads to include the paved surface up to the front entrance of the hospital because this portion of the distance is utilized by the public to access the hospital. This definition provides consistency with the interpretation of the MGCRB when considering hospital reclassification applications. The MGCRB measures the distance between the hospital and the county line of the area to which it seeks reclassification beginning with the paved area outside the front entrance of

the hospital. This provides a consistent, national definition that is easily recognizable for each hospital. Finally, rounding of mileage is not permissible. This is also consistent with the MGCRB definition of mileage (56 FR 25483). In this final rule, we are revising the definition of ''miles'' under § 412.92(c)(1) to state that an improved road includes the paved surface up to the front entrance of the hospital.

Under § 412.92(c)(2), we define ''like'' hospital. We consider like hospitals to be those hospitals furnishing short-term acute care. That is, a hospital may not qualify for an SCH classification on the grounds that neighboring hospitals offer specialty services, thereby seeking to exclude close-by competitors as like hospitals, in order to meet the mileage criteria by measuring to a like hospital that is located further away. For example, we believe that competing hospitals within a given area may each have their own specialty services, while all the facilities continue to be considered short-term acute care hospitals. We note that under § 412.92(a)(1)(ii), a hospital with fewer than 50 beds may qualify for SCH status under a special provision if patients that it would normally serve are seeking care elsewhere due to the unavailability of specialty services. This means that, if a hospital can prove that the patients from its service area are seeking specialty services elsewhere (such as, among others, heart surgery, transplants, and burn care), rather than routine care, and, because of that fact, that it otherwise would have met the criteria of section § 412.92(a)(1)(i), it can qualify as an SCH.

We note that § 412.92(b)(1)(iii)(A) retains an outdated reference to ''hospitals located within a 50 mile radius of the hospital.'' With the issuance of the September 1, 1989 **Federal Register** (54 FR 36481, 36482), the 50 mile radius was determined to be unreasonable and all references should have been changed to 35 miles in accordance with § 412.92(a)(1)(i). In this final rule. we are revising the reference to ''a 50 mile radius'' in § 412.92(b)(1)(iii)(A) to read ''a 35 mile radius''.

We note that the travel time and weather conditions criteria set forth in § 412.92(a)(3) were discussed in detail in the September 4, 1990 **Federal Register** (55 FR 36050 through 36055 and 36162 through 36163).

Under § 412.92(a)(1)(i) and (b)(1)(ii), we define the market area analysis criteria used to determine SCH status. In the May 4, 2001 proposed rule, we discussed several points concerning these requests for SCH status that we proposed to clarify.

First, a hospital seeking an SCH designation based on these criteria must make its initial request to the fiscal intermediary with all the appropriate documents as will be discussed below (§ 412.92(b)(1)(i)). The fiscal intermediary will make a recommendation on the request, based on receipt of all the appropriate documentation and its own investigation and analysis, and that recommendation will be forwarded to the CMS regional office for another level of review and final approval or disapproval. The fiscal intermediary would forward its recommendation to the CMS regional office located in the hospital's area as opposed to the fiscal intermediary's area, if there is a difference in these areas. As discussed above, an approval of the request for SCH status will be effective 30 days after CMS issues the approval letter. If a determination on the request requires the use of data that are available at CMS central office only, upon receipt of the fiscal intermediary's recommendation, the CMS regional office will forward the request and the fiscal intermediary's recommendation to the appropriate contact at CMS central office where the determination will be made.

Second, a hospital must provide patient origin data (the number of patients from each zip code from which the hospital draws inpatients) for all inpatient discharges to document the boundaries of its service area (§ 412.92(b)(1)(ii)(A)). Or, the hospital can request that CMS develop patient origin data to define its service area based on the number of patients from each zip code from which the hospital draws Medicare Part A inpatients (§ 412.92(b)(1)(iii)). Then, the lowest number of zip codes in descending percentage order of Medicare inpatients that meets the 75-percent threshold will be used to represent the hospital's service area. We note that hospitals cannot substitute zip codes elsewhere on the list in order to manipulate the service area. (See *Howard Young Medical Center, Inc.* v. *Shalala*, 207 F.3d 437 (7th Cir. 2000).)

Third, the hospital must provide patient origin data from all other hospitals located within a 35-mile radius of it or, if larger, within its service area, to document that no more than 25 percent of either all of the population or the Medicare beneficiaries residing in the hospital's service area and hospitalized for inpatient care were admitted to other like hospitals for care (§ 412.92(b)(1)(ii)(B)). Again, CMS central office can develop patient origin data for other hospitals within the requesting hospital's service area if the hospital is requesting SCH status based on an examination of Medicare Part A inpatient utilization. In either case, the requesting hospital is required to submit a comprehensive list of hospitals located within a 35-mile radius or, if larger, within its service area. This list will be checked by both the fiscal intermediary and CMS. Again, a requesting hospital cannot argue that a competing hospital should be excluded from the service area based on the existence of specialty services at that hospital if both hospitals are short-term acute care facilities. Distances between all reported hospitals will be checked by both the fiscal intermediary and CMS, through electronic geographic mapping services (such as Yahoo or Mapquest) or by physically driving the distance involved.

In addition, data will be analyzed based on the year for which the hospital requests SCH status. Subsequent hospital mergers or terminations will not be taken into consideration in processing the request. For example, if a hospital requests SCH status using data for FY 1999, and that data show that there is a competing hospital in existence that subsequently closed its doors in FY 2000, the data will be analyzed with the terminated hospital in existence, unless the hospital seeking SCH status applies using later data, such as FY 2001. This principle is consistent with how we analyze wage index data. If a terminated hospital has a viable cost report for the year of wage data that is being analyzed to produce the wage index, its data are included as part of the computation.

We received the following comments on our May 4, 2001 proposed rule and the June 13, 2001 interim final rule with comment period:

Comment: Several commenters were concerned with the following issues related to the qualifying criteria for sole community hospitals: (1) Utilizing TAC worksheets or other data sources in order to develop a base year alternative for a new SCH; (2) determining a service area; (3) recognition of hospital mergers and terminations that influence a hospital seeking SCH status; (4) including competing hospitals within a 35-mile radius of the requesting hospital as opposed to a 35-road-mile distance; (5) obtaining patient origin data from competing hospitals, (6) timeliness of SCH approvals; (7) SCH status for hospitals with fewer than 50 beds; (8) CAHs as like hospitals; (9) the effect of wage index reclassifications on a hospital's SCH status; and (10) the use of affidavits and other certifications in

verifying time and distance when applying for SCH status.

Response: We would like to reiterate that in the proposed rule we were restating historical and current policy and criteria for SCHs. We were not proposing new SCH policies or criteria, or revisions to existing policies or criteria. Rather, we were striving to publish criteria that has been developed over the past several years in one location for the reader's benefit.

First, we appreciate the input concerning a hospital's access to alternative data when a cost report from a prior year may not be readily available. We will take this comment into consideration in working with the fiscal intermediaries in the future to adjust a SCH's payments.

Second, we believe that, using discharge data available on the MedPAR file, we can accurately determine a hospital's service area based on the zip codes that contain the highest number of discharges for that facility and rank those zip codes accordingly. Several commenters suggested that we use patient destination data that are available in some States and, also, that we not be concerned if these data were not available based on a hospital's cost reporting period. As in other aspects of the Medicare program, we must rely on data that are consistent, verifiable by the fiscal intermediaries, and nationally available so that no one hospital or group of hospitals receives a distinct advantage by using an alternative source of data that is not widely available. Therefore, we believe that it is appropriate to determine the hospital's service area based on Medicare discharges.

Third, if a hospital chooses to have a merger recognized in its request for SCH status, or, likewise, a hospital termination, then it is free to wait until its cost report data reflects these changes. Then, CMS will consider the data in light of these facts.

Fourth, we believe it is reasonable to examine a hospital's competitors within a 35-mile radius. Most competing hospitals will not be at the outer limit of the 35-mile radius, and, if these hospitals are not truly competitors, the discharge data will bear out that fact. Also, we examine a hospital's service area based on discharges within zip code areas, and, often, this will exceed a 35-mile radius. Therefore, we believe the 35-mile radius is reasonable.

Fifth, we realize that obtaining patient origin data from competing hospitals may be a difficult proposition, which is why CMS offers to provide this information for the requesting hospital in § 412.92(b)(1)(iii)(A). CMS' data are based on Medicare discharges.

Sixth, approvals of SCH status are effective prospectively. There are several ways in which a hospital may qualify as a SCH, and fiscal intermediaries are required to collect and examine detailed documentation which sometimes requires the assistance of our regional or central office staff. We appreciate the fact that hospitals are concerned that their applications be approved in a timely manner, and we will make every effort to work diligently with our contractors as well as our regional offices to achieve that goal.

Seventh, a commenter suggested that we should be more specific when defining the criteria under which a hospital with fewer than 50 beds could qualify as an SCH at § 412.92(a)(ii). We will take this into consideration as we develop further criteria in the future. In the meantime, we will continue to work closely with our fiscal intermediaries in approving a hospital's SCH status under this provision.

Eighth, we do not consider CAHs like hospitals to be SCHs. CAHs are generally smaller with a very limited length of stay, while SCHs operate as full-service acute-care hospitals.

Ninth, a hospital's status as an SCH is not affected by a wage index reclassification approved by the MGCRB. A hospital's SCH status is affected by an approval for a standardized amount reclassification only, as a reclassification for purposes of a hospital's base payment rate changes its status for all inpatient hospital prospective payment purposes except the wage index.

Finally, hospitals are encouraged to provide as much documentation as possible to assist the fiscal intermediary and CMS in evaluating requests for SCH status. The more complete the documentation, the quicker a decision can be rendered. If a hospital can provide affidavits or other verification of mileage, distances, competing hospital locations, etc., then it is encouraged to do so.

B. Rural Referral Centers (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria a hospital must meet in order to receive special treatment under the prospective payment system as a rural referral center. For discharges occurring before October 1, 1994, rural referral centers received the benefit of payment based on the other urban amount rather than the rural standardized amount. Although the other urban and rural standardized amounts were the same for discharges beginning with that date, rural referral centers would continue to receive special treatment under both the disproportionate share hospital (DSH) payment adjustment and the criteria for geographic reclassification.

Section 401 of Public Law 106–113 amended section 1886(d)(8) of the Act by adding subparagraph (E), which creates a mechanism, separate and apart from the MGCRB, permitting an urban hospital to apply to the Secretary to be treated as being located in the rural area of the State in which the hospital is located. The statute directs the Secretary to treat a qualifying hospital as being located in the rural area for purposes of provisions under section 1886(d) of the Act. Congress clearly intended hospitals that become rural under section 1886(d)(8)(E) of the Act to receive some benefit as a result. In addition, one of the criteria under section 1886(d)(8)(E) of the Act is that the hospital would qualify as an SCH or a rural referral center if it were located in a rural area. An SCH would be eligible to be paid on the basis of the higher of its hospital-specific rate or the Federal rate. On the other hand, the only benefit under section 1886(d) of the Act for an urban hospital to become a rural referral center would be waiver of the proximity requirements that are otherwise applicable under the MGCRB process, as set forth in § 412.230(a)(3)(i).

In the August 1, 2000 final rule (65 FR 47089), we stated that we believed Congress contemplated that hospitals might seek to be reclassified as rural under section 1886(d)(8)(E) of the Act in order to become rural referral centers so that the hospitals would be exempt from the MGCRB proximity requirement and could be reclassified by the MGCRB to another urban area. Therefore, in that final rule we sought a policy approach that would appropriately address our concern that these urban to rural redesignations not be utilized inappropriately, and that would benefit hospitals seeking to reclassify under the MGCRB process by achieving rural referral center status. (We became aware of several specific hospitals that were rural referral centers for FY 1991, but subsequently lost their status when the county in which they were located became urban, and had expressed their wish to be redesignated as a rural referral center in order to be eligible to reclassify.) Accordingly, in light of section 1886(d)(8)(E) of the Act and the language in the accompanying Conference Report, effective as of October 1, 2000, hospitals located in what is now an urban area, if they were ever a rural referral center, were reinstated to rural referral center status.